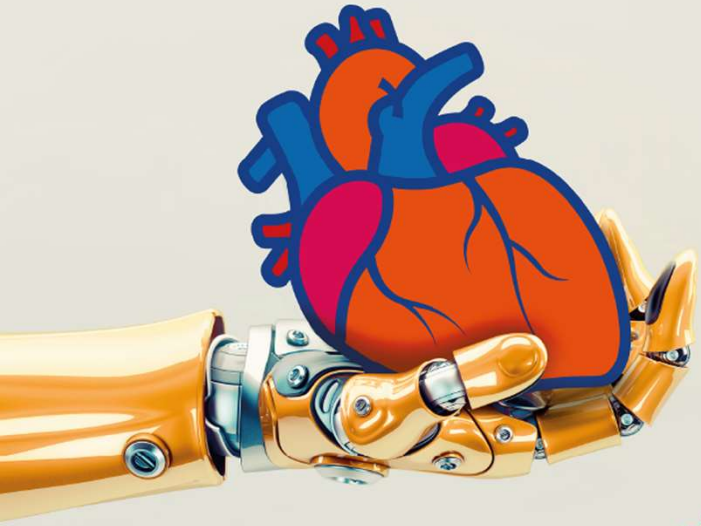

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Heart Brings Heart 2023

Lucca, 22-24 Giugno 2023

Centro Congressi Auditorium San Francesco

Massimo Fineschi
Cardiologia Interventistica
AOUS Siena

Appropriatezza dell'imaging per ottimizzare le procedure di interventistica coronarica

Clinical use of intracoronary imaging

- Randomized controlled trials and registries consistently support procedural and long-term benefit with the use of intravascular imaging (IVI) for percutaneous coronary intervention (PCI) guidance

- The benefits of intracoronary imaging depend largely on the interpretation and the operator's reaction to these findings. Imaging acquisition alone will not be sufficient to impact on outcome !

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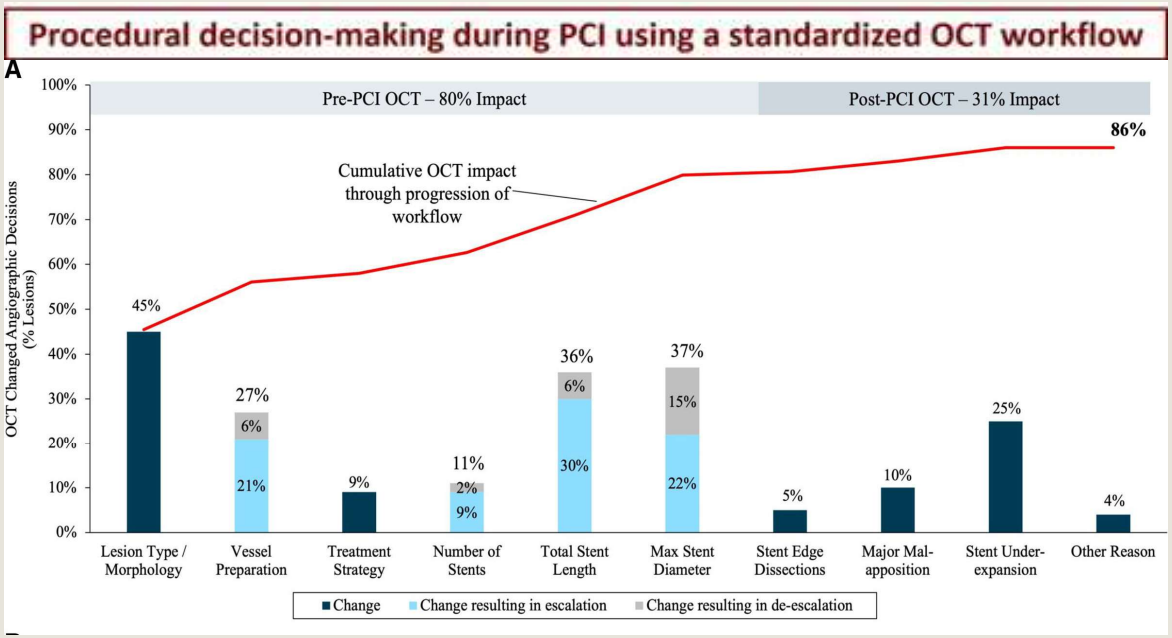
Circulation: Cardiovascular Interventions
Volume 15, Issue 11, November 2022; Pages 872-881

CORONARY PHYSIOLOGIC ASSESSMENT AND IMAGINGS

Decision-Making During Percutaneous Coronary Intervention Guided by Optical Coherence Tomography: Insights From the LightLab Initiative

See Editorial by Razzouk and Attubato

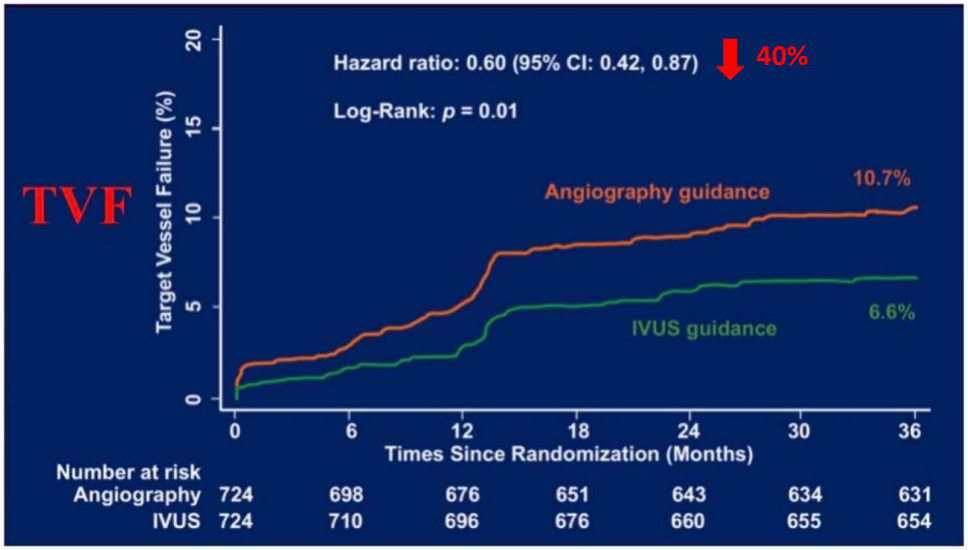
Brian Bergmark, MD, Luis A.P. Dallan, MD, PhD, Gabriel T.R. Pereira, MD, Julia F. Kuder, MA, Sabina A. Murphy, MPH, Jana Buccola, MS, Jason Wollmuth, MD, John Lopez, MD, Joia Spinelli, BS, Jennifer Meinen, BS, Nick E.J. West, MD, Kevin Croce, MD, PhD, and on behalf of the LightLab Initiative Investigators



16 centers in US-173 procedures-836 lesions

ULTIMATE

3-year Clinical FU



ORIGINAL ARTICLE FREE PREVIEW

Intravascular Imaging–Guided or Angiography-Guided Complex PCI

Joo Myung Lee, M.D., Ph.D., M.P.H., Ki Hong Choi, M.D., Ph.D., Young Bin Song, M.D., Ph.D., Jong-Young Lee, M.D., Ph.D., Seung-Jae Lee, M.D., Ph.D., Sang Yeub Lee, M.D., Ph.D., Sang Min Kim, M.D., Ph.D., Kyeong Ho Yun, M.D., Ph.D., Jae Young Cho, M.D., Ph.D., Chan Joon Kim, M.D., Ph.D., Hyo-Suk Ahn, M.D., Ph.D., Chang-Wook Nam, M.D., Ph.D., et al., for the RENOVATE-COMPLEX-PCI Investigators*

Objective: to investigate whether intravascular imaging PCI using IVUS or OCT would improve clinical outcomes compared with angiography guided PCI in patients with complex artery lesions

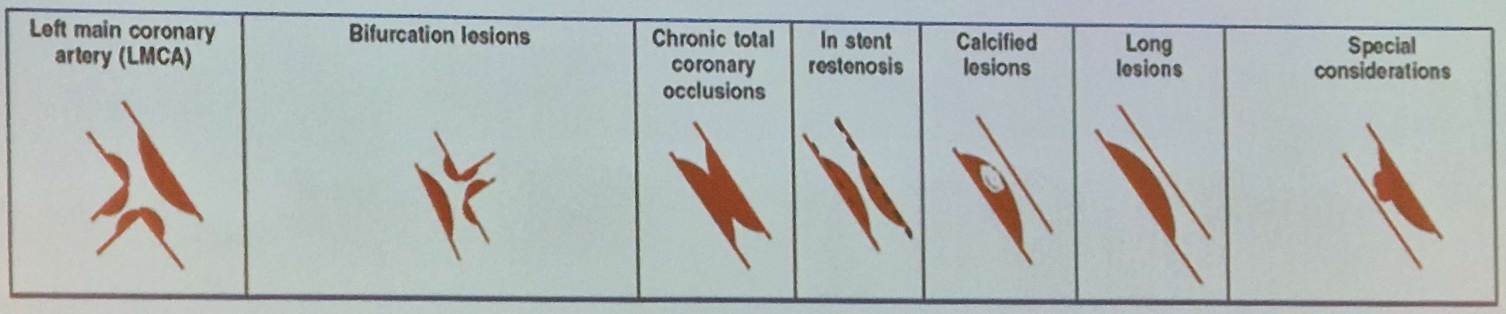
Primary Hypothesis

Intravascular imaging-guided PCI would reduce TVF compared with angiography-guided PCI
In treatment of patients with **complex coronary artery lesions**

Study design

RENOVATE-COMPLEX-PCI Trial (NCT03381872)

1,620 Patients with Complex Coronary Artery Lesions Undergoing PCI



Randomization (2:1) for Treatment Strategy of Target Lesions
(Stratified by acute coronary syndrome and participating centers)

Imaging-Guided Strategy	Angiography-Guided Strategy
N = 1,080	N = 540

All patients were followed until 1 year after last patient enrollment.

ACC.23 WCC

Lee JM, Choi KH, Song YB, Hahn JY, et al. NEJM 2023

Study endpoints

Primary End Point

- **Target vessel failure**
  - A composite of cardiac death, target vessel-related MI, and clinically-driven target vessel revascularization.

Secondary End Point

- Target vessel failure without procedure-related MI
- Cardiac death or target vessel-related MI
- Target vessel-related MI with or without procedure-related MI
- Non-target vessel-related MI
- Any MI with or without procedure-related MI
- Target lesion revascularization
- Target vessel revascularization
- Any revascularization (clinically-driven)
- Definite stent thrombosis
- Total amount of contrast
- Incidence of contrast-induced nephropathy
- Total procedural time
- Total medical cost (not reported in this publication)

Definition of Clinical Events

- Spontaneous MI according to 3rd Universal Definition[1]
- Other clinical events according to ARC-2 criteria[3]
- Procedure-related MI according to SCAI Definition[2]

ACC.23 TOGETHER WITH WCC

Lee JM, Choi KH, Song YB , Hahn JY, et al. NEJM 2023

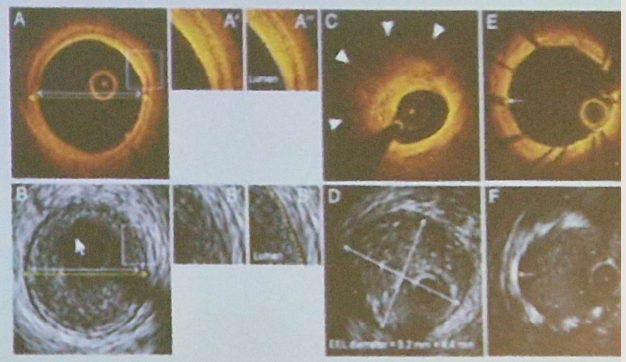
Procedures

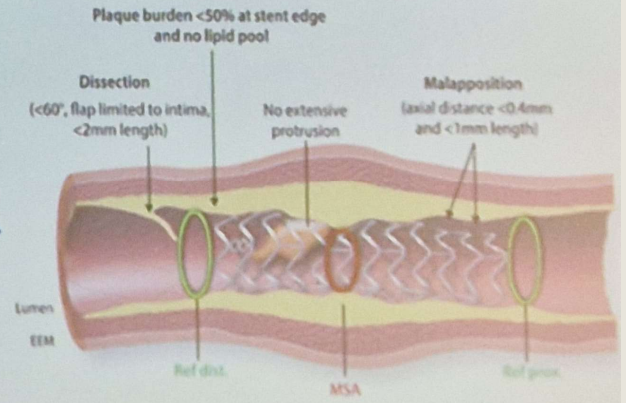
ACC.23 TOGETHER WITH WCC

Standardized Protocols of Intravascular Imaging and Optimization

	IVUS	OCT
Reference Sites	Largest size vessel lumen	Most normal looking segment
	Plaque burden <50%	No lipid-containing plaque
	At least 5 mm apart from target lesion	At least 5 mm apart from target lesion
Stent Sizing	By mean EEM diameter of proximal and distal reference segment	By mean EEM diameter at distal reference segment (rounded down to the nearest 0.25 mm). By mean Lumen diameter at distal reference segment (rounded up to the nearest 0.25 mm).
Stent Length	By measuring the distance from the distal to the proximal reference site.	
Stent Optimization		
• **Stent Expansion**	Visually assess that the residual angiographic diameter stenosis is <10% "AND" • Non-left main coronary artery lesions: MSA > 80% of the average reference lumen area "OR" a MSA of >5.5 mm² by IVUS and >4.5 mm² by OCT. • Left main coronary artery lesions: MSA of >7 mm² for a distal left main coronary artery stenosis and >8 mm² for a proximal left main coronary artery stenosis by IVUS.	
• **Stent Apposition**	No major malapposition (defined as an acute malapposition of ≥0.4 mm with longitudinal extension >1 mm) of the stent over its entire length against the vessel wall.	
• **Edge Dissection**	No major edge dissection in the proximal or distal reference segments, defined as a location that is 5 mm from the edge of the stent, extends to the medial layer with potential to provoke flow disturbances (defined as ≥60° of the circumference of the vessel at site of dissection and/or ≥3 mm in length of the dissection flap)	
Additional Procedure	**If any of above findings are identified, additional procedural intervention, including additional post-dilatation of the stent or additional stent implantation is recommended.**	

Raber L, Mintz GS, Koskinas KC, et al. Eur Heart J 2018;39:3281-300.





Lee JM, Choi KH, Song YB , Hahn JY, et al. NEJM 2023

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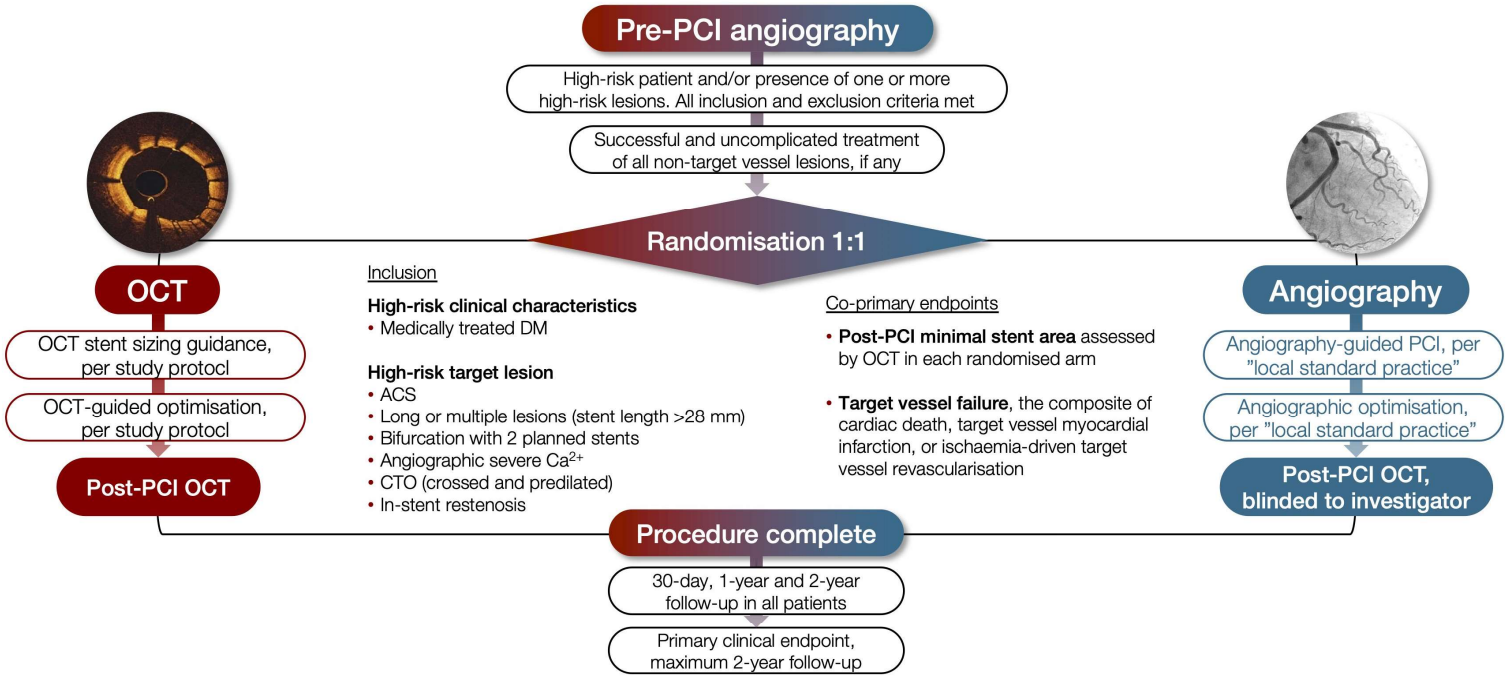
ILUMIEN IV: HYPOTHESIS

In high-risk patients and complex lesions, OCT-guided PCI compared to angiography-guided PCI will reduce TVF.

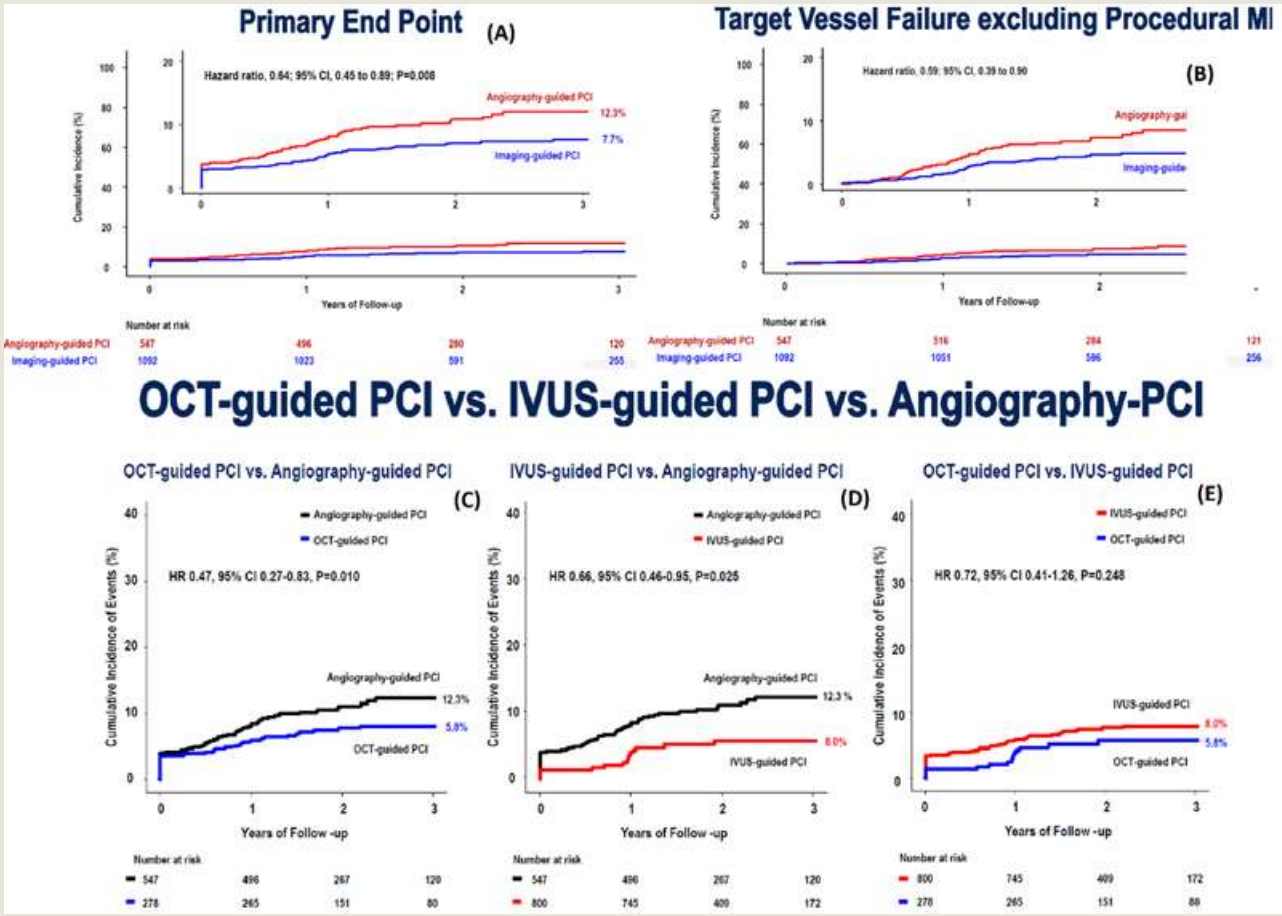
EuroIntervention | **TOP CITED 2022** ☆☆☆

VISUAL ILLUSTRATION. Optical Coherence Tomography-guided Coronary Sten
Compared to Angiography: Design and Rationale of ILUMIEN IV: OPTIMAL PCI

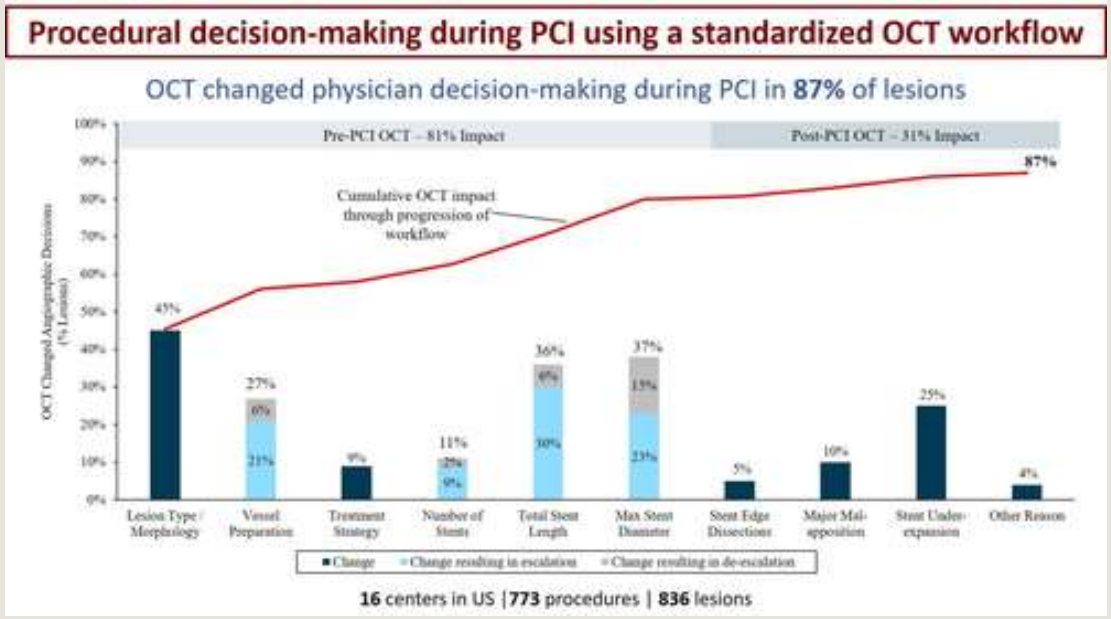


Abbreviations: ACS, acute coronary syndrome; CTO, chronic total occlusion; DM, diabetes mellitus; OCT, optical coherence tomography; PCI, percutaneous coronary intervention.

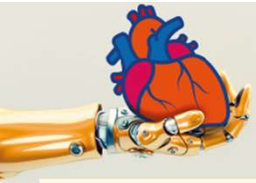
Use of intravascular optical coherence tomography or intravascular ultrasound to guide stent implantation. The choice is yours!



The benefits of intracoronary imaging depend largely on the interpretation and the operator's reaction to these findings. Imaging acquisition alone will not be sufficient to impact on outcome !



Brian Bergmark. Circulation: Cardiovascular Interventions. Decision-Making During Percutaneous Coronary Intervention Guided by Optical Coherence Tomography: Insights From the LightLab Initiative, Volume: 15, Issue: 11, Pages: 872-881, DOI: (10.1161/CIRCINTERVENTIONS.122.011851)



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CENTRAL ILLUSTRATION IVUS and OCT: Similarities and Differences

OCT				IVUS		
Very good	Good	Feasible		Feasible	Good	Very good
			Pre-PCI			
●	●	●	← Severity of calcium	●	●	
		●	Prediction of slow flow	●		
	●	●	Stent sizing by vessel wall →	●	●	●
●	●	●	Stent length to cover normal to normal	●	●	●
			Post-PCI			
●	●	●	Stent expansion	●	●	●
●	●	●	Tissue protrusion through strut	●	●	
●	●	●	Stent malapposition	●	●	
	●	●	Stent deformation (frequently at aorto-ostium)	●	●	
●	●	●	Stent edge dissection	●	●	
●	●	●	Residual disease at stent edge	●	●	●
			Follow-up			
●	●	●	Old stent expansion	●	●	●
	●	●	← Tissue coverage	●		
●	●	●	Neointimal hyperplasia	●	●	●
	●	●	Stent fracture	●	●	
●	●	●	Stent malapposition	●	●	
		●	Positive remodeling of vessel wall →	●	●	●
●	●	●	Neoatherosclerosis	●	●	

Maehara, A. et al. J Am Coll Cardiol Img. 2017;10(12):1487-503.

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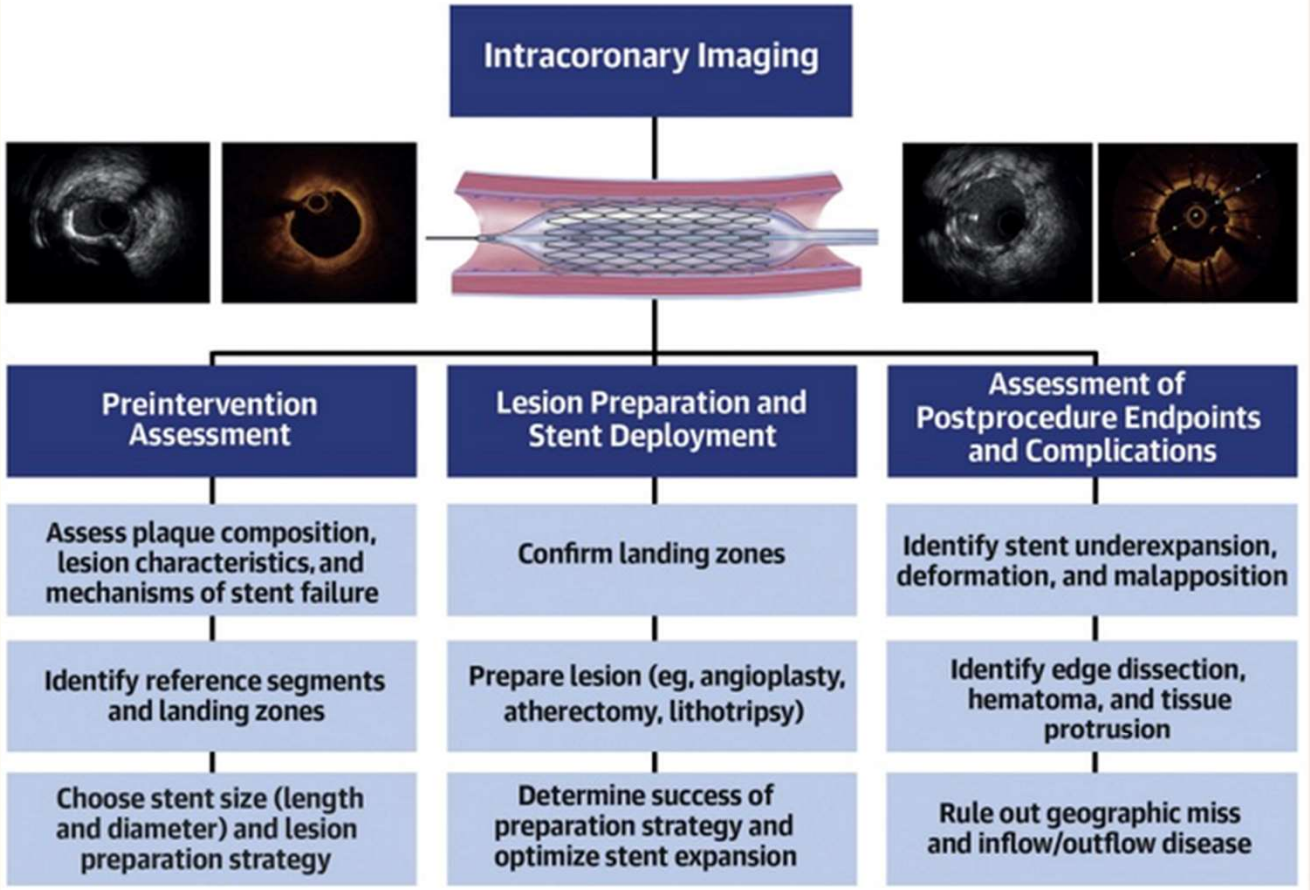
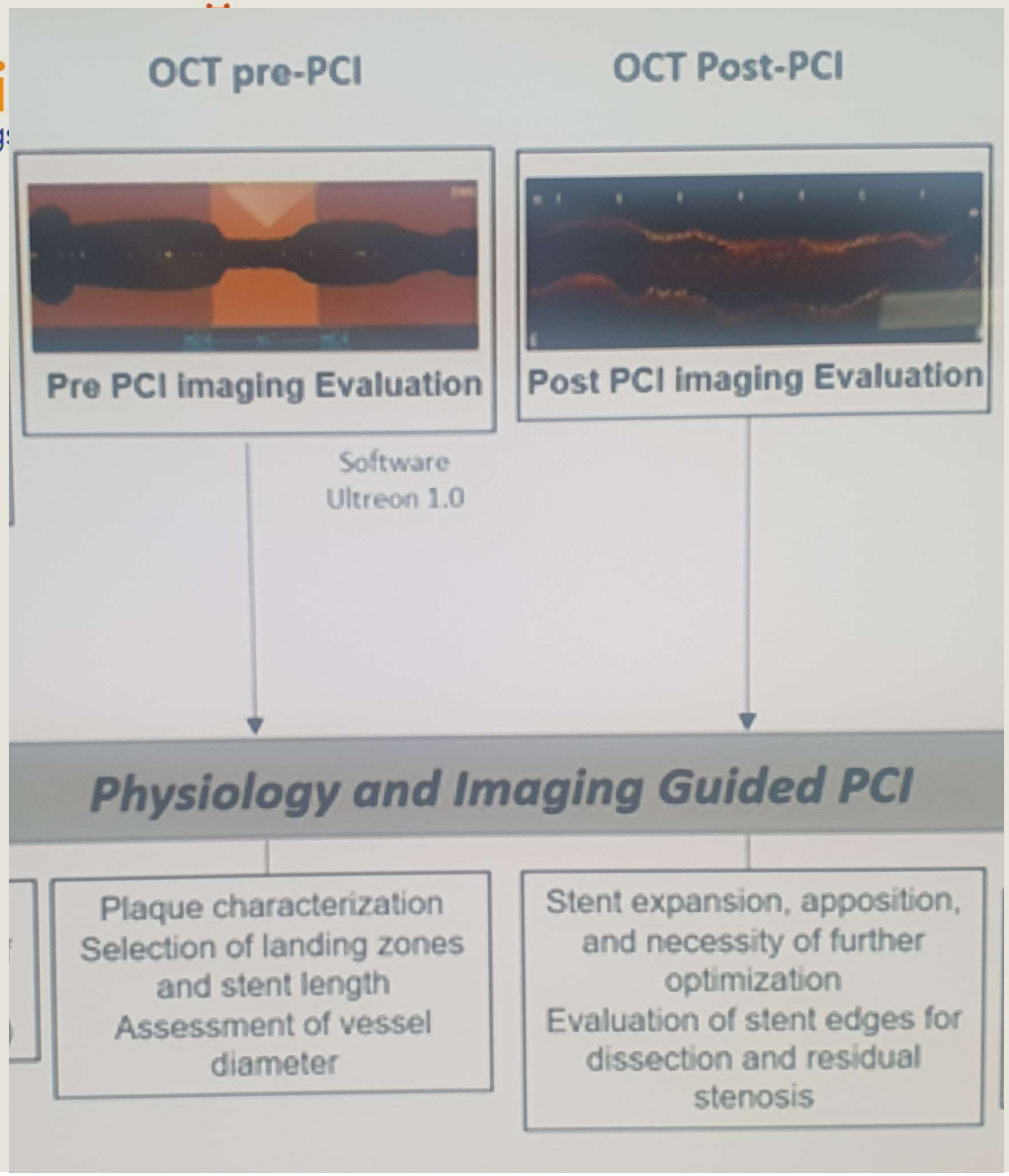
CENTRAL ILLUSTRATION: Best Practice Summary for Use of Intracoronary Imaging



Truesdell AG, et al. J Am Coll Cardiol. 2023;81(6):590-605.


OCT pre-PCI
OCT Post-PCI
Pre PCI imaging Evaluation
Post PCI imaging Evaluation
Software
Ultreon 1.0
Physiology and Imaging Guided PCI
Plaque characterization
Selection of landing zones and stent length
Assessment of vessel diameter
Stent expansion, apposition, and necessity of further optimization
Evaluation of stent edges for dissection and residual stenosis

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Modern OCT Guided PCI Workflow | MLD MAX

Each OCT run serves a separate purpose. The pre-PCI run helps determine the PCI strategy, and the post-PCI run allows for optimization of the stent as needed.

Pre-PCI OCT | Strategize

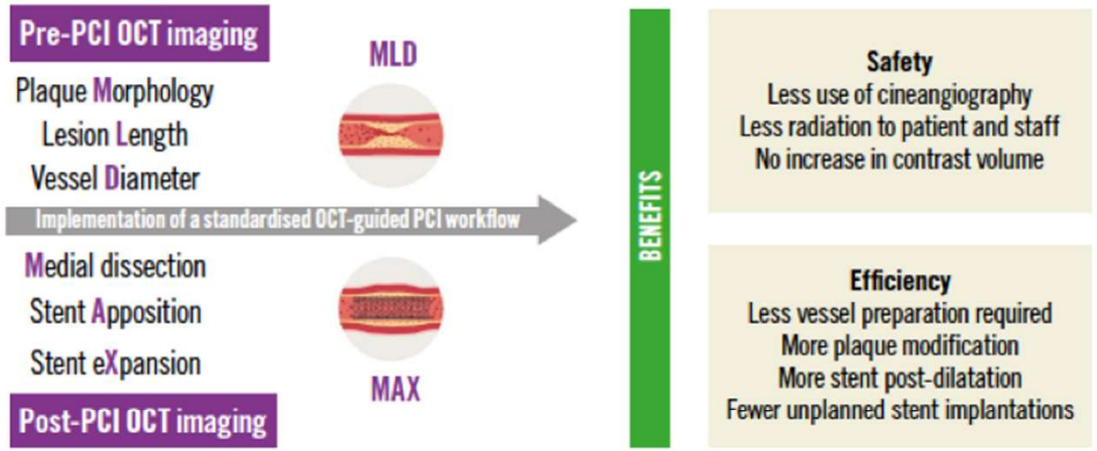
- **M**ORPHOLOGY
- **L**ENGTH
- **D**IAMETER

Post-PCI OCT | Optimize

- **M**EDIAL DISSECTION
- **A**PPOSITION
- e**X**PANSION

EuroIntervention

CENTRAL ILLUSTRATION Impact of a standardised OCT-guided PCI workflow on procedural safety and efficacy.



Clinical safety and procedural efficiency benefits are evident with a standardised pre- and post-PCI OCT imaging workflow that optimises coronary stent implantation. OCT: optical coherence tomography; PCI: percutaneous coronary intervention

1. Morphology
Assess Plaque Composition

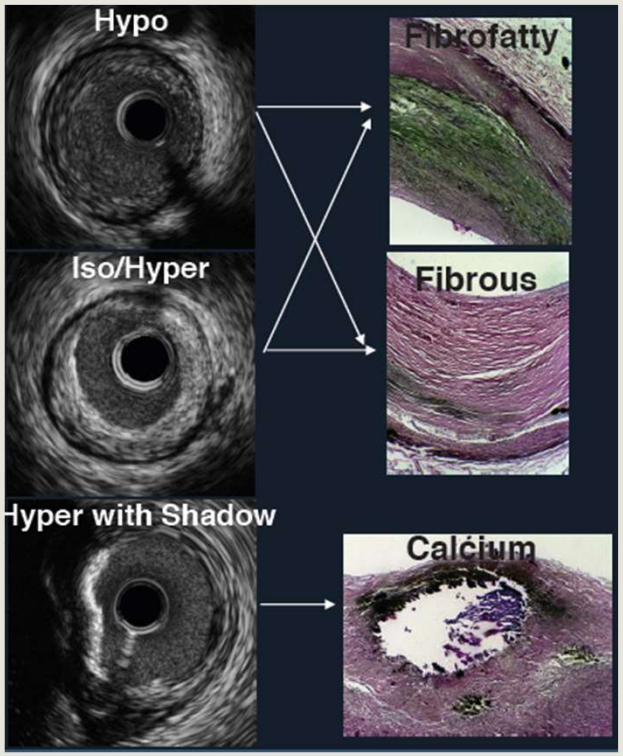
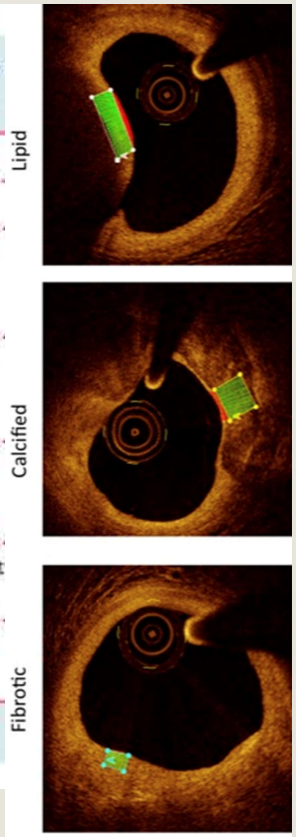


Table 2 Image characteristics of optical coherence tomography vs. IVUS

Tissue type	Image characteristics	
	OCT	IVUS
Fibre	Homogeneous High reflectivity Low attenuation	Homogeneous High reflectivity
Calcium	Sharp edges Low reflectivity Low attenuation	Very high reflectivity Shadowing
Lipid	Diffuse edges High reflectivity High attenuation	Low backscatter
Red thrombus	Medium reflectivity High attenuation	Medium-high reflectivit
White thrombus	Medium reflectivity Low attenuation	

OCT, optical coherence tomography.



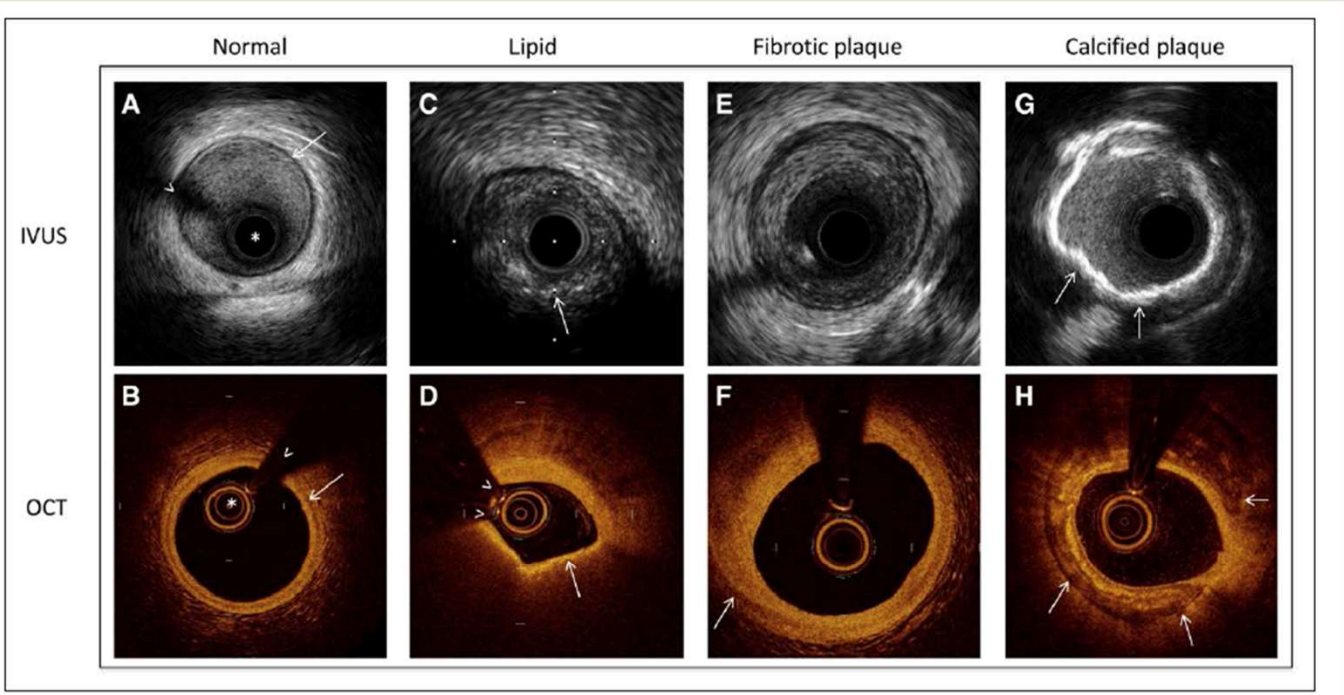
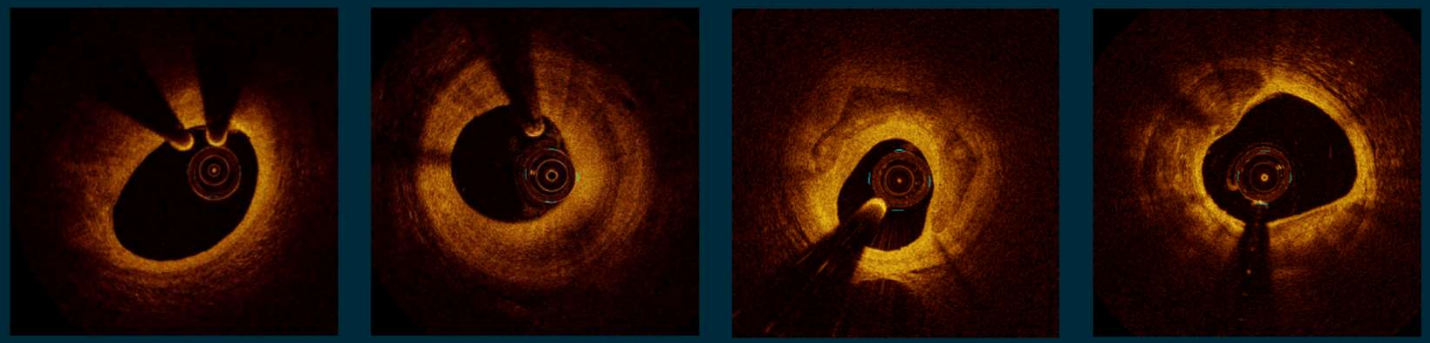


Figure 1. **Lesion morphology appearance with intravascular imaging.**

Morphology Guided Lesion Preparation



Lipidic | Fibrotic | Mild/Moderate Ca^{2+} | Severe Ca^{2+}

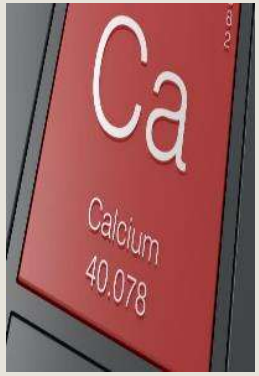
DIRECT STENTING[1]

COMPLIANT BALLOON[2]

NON-COMPLIANT BALLOON[3]

ATHERECTOMY OR IVL[4]

THE CALCIUM PROBLEM



ABSENCE OF INTRAVASCULAR IMAGING

↓

UNDERESTIMATION OF CALCIUM

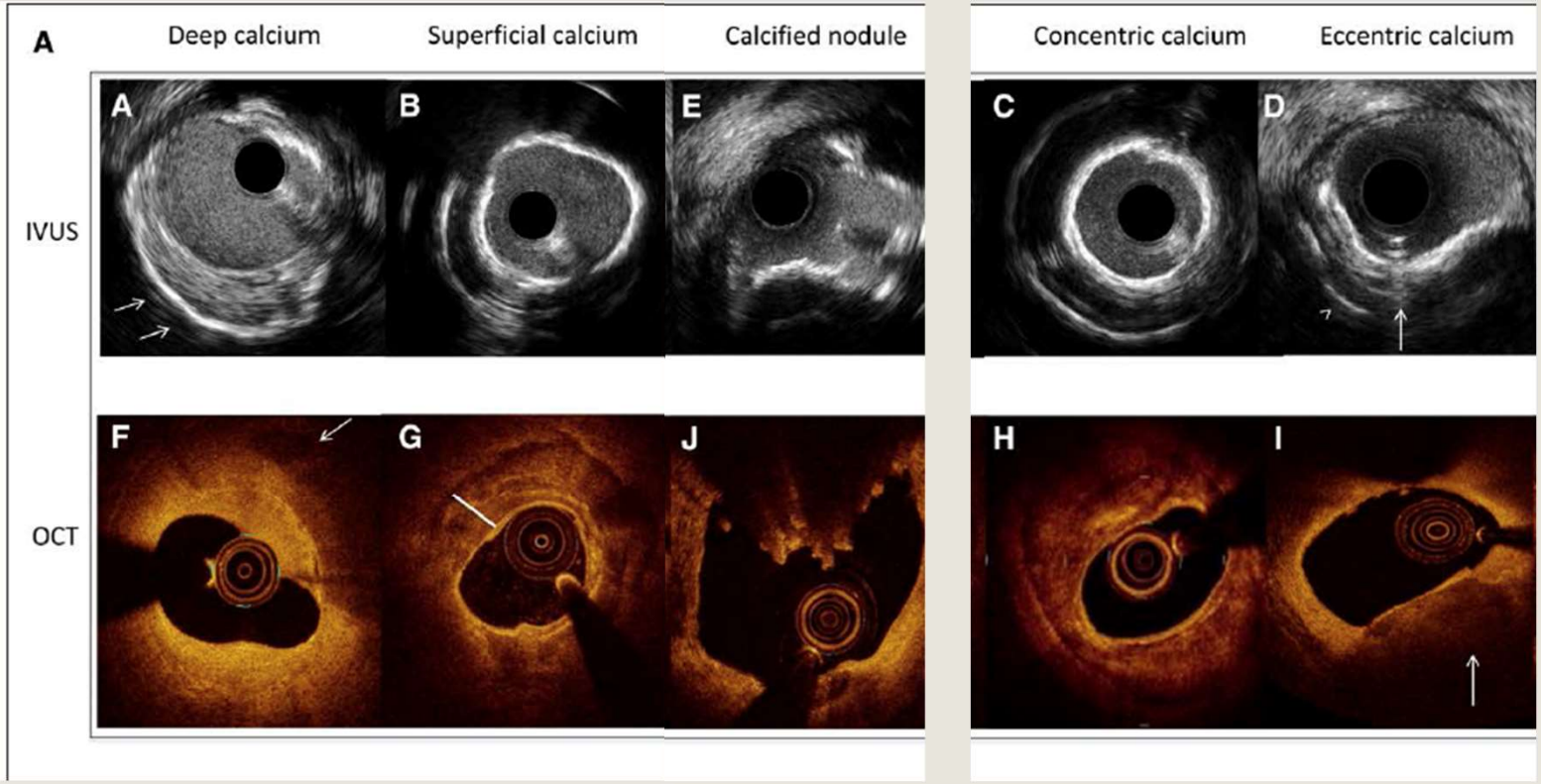
↓

INCREASED LIKELIHOOD OF IMPROPER VESSEL PREP

↓

- **STENT UNDEREXPANSION**
- **INCREASE RISK OF COMPLICATIONS**
- **STENT MALAPPOSITION**
- **MORE STENTS**
- **LONGER PROCEDURES**

PRE-PCI detection af calcium
DEFINE TYPE CALCIUM…



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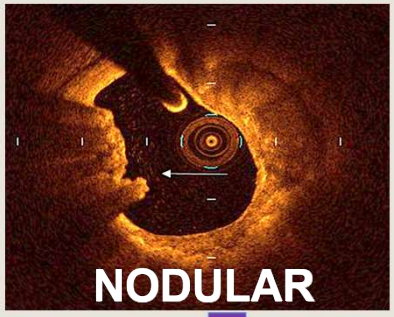
DEFINE TYPE CALCIUM…

ROLE FOR CALCIUM MODIFICATION

NON- ROLE
NC/SCORING/CUTTING

ROLE
ROTATIONAL/ORBITAL/
LITHOTRIPSY/EXCIMER
LASER



TRADITIONAL ATHERECTOMY
ROTATIONAL/ORBITAL

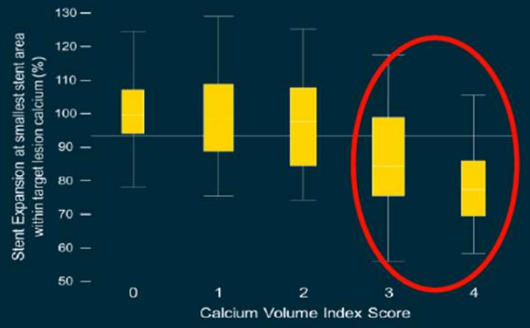
Influence of Ca^{2+} on Stent Expansion by OCT

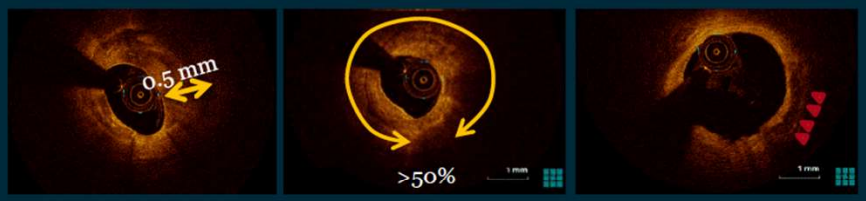
OCT-Based Calcium Volume Index Score[1]

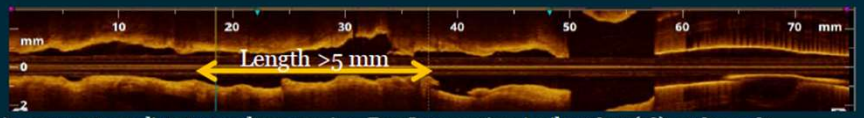
1. Maximum Calcium Angle (°)	≤ 90°	0 point
	90° < Angle ≤ 180°	1 point
	> 180°	2 points
2. Maximum Calcium Thickness (mm)	≤ 0.5 mm	0 point
	> 0.5 mm	1 point
3. Calcium Length (mm)	≤ 5.0 mm	0 point
	> 5.0 mm	1 point
Total score	**0 to 4 points**	

Rule of 5's

- 0.5 mm thickness
- 5.0 mm long
- 50% vessel arc



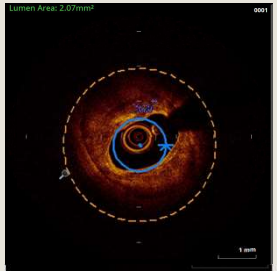




1. Fujino, A. et al. A new optical coherence tomography-based calcium scoring system to predict stent under expansion. *EuroIntervention*, April 2018; 13(18):e2182-e2189.

SCORE THE CALCIUM…

TOTAL = 4 POINTS



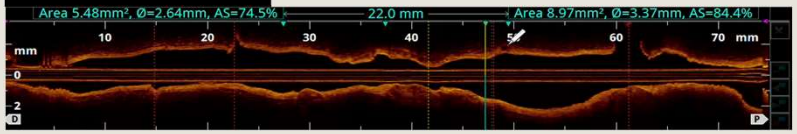
1. Maximum Calcium Angle (°)

360° ARC ⇨ 2 points

(>180° arc, >5mm long, >0.5mm thick)

2. Maximum Calcium Thickness (mm)

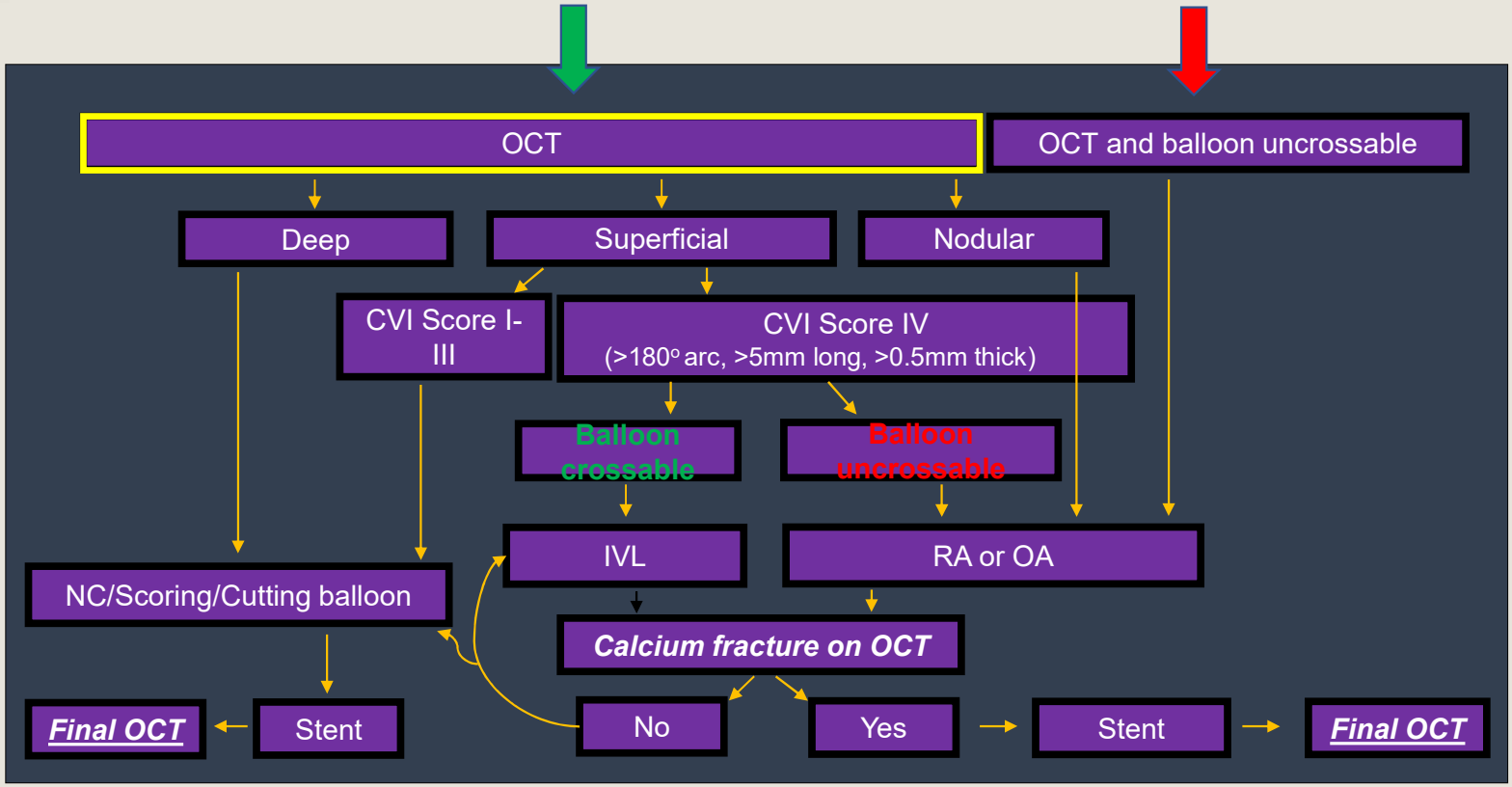
1.31mm ⇨ 1 point



3. Calcium Length (mm)

9.90mm ⇨ 1 point

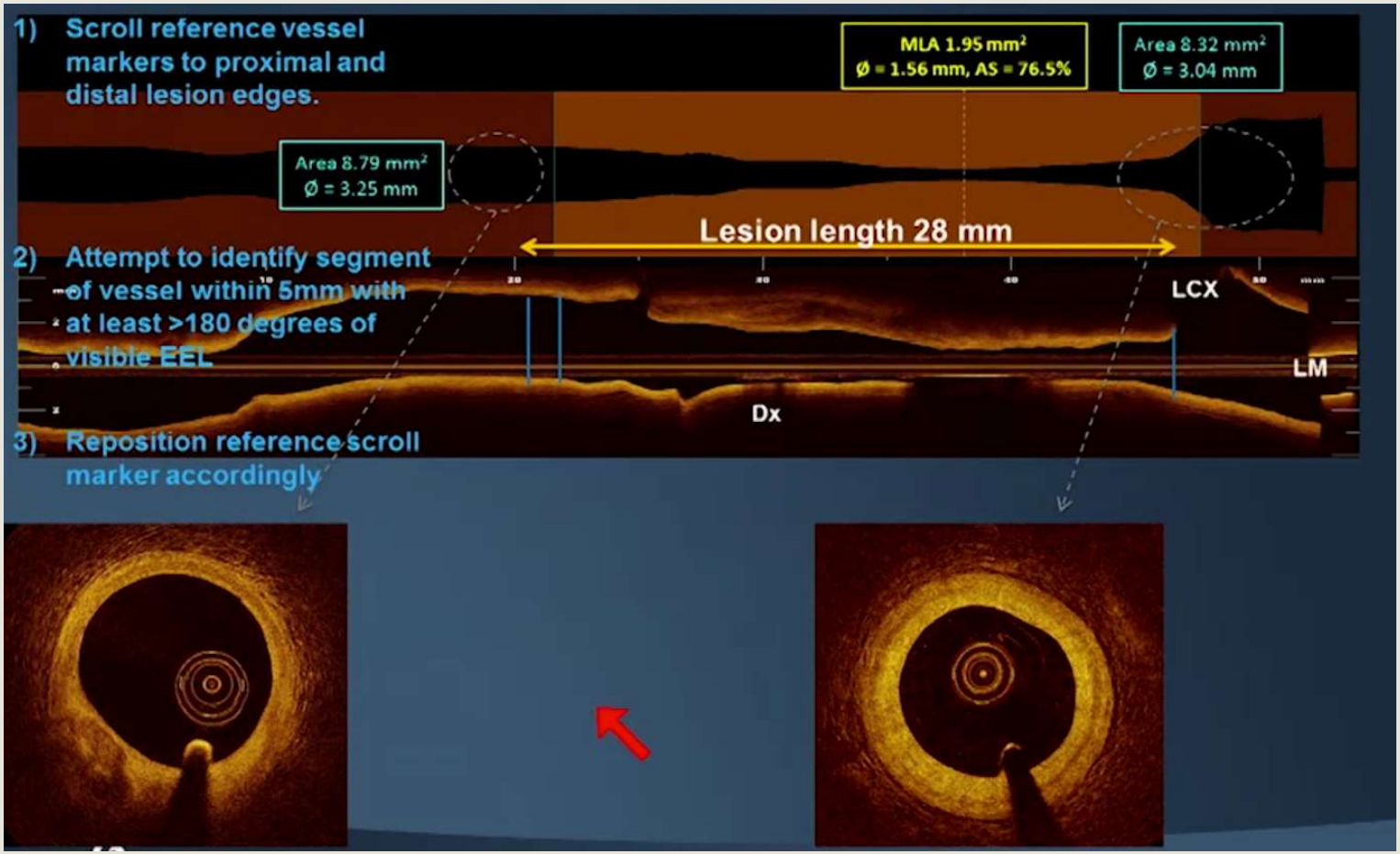
PRESCRIPTIVE ALGORITHM FOR TREATMENT OF CALCIFIED LESIONS



Shlofmitz et al. *Curr Cardiovasc Imaging Rep*. 2019

2.Identify Reference Segments (Prox & Dist)

Choose Stent Length: avoidance the landing zone within an area of residual plaque burden >50% and particularly lipid-rich plaque



2.Lenght

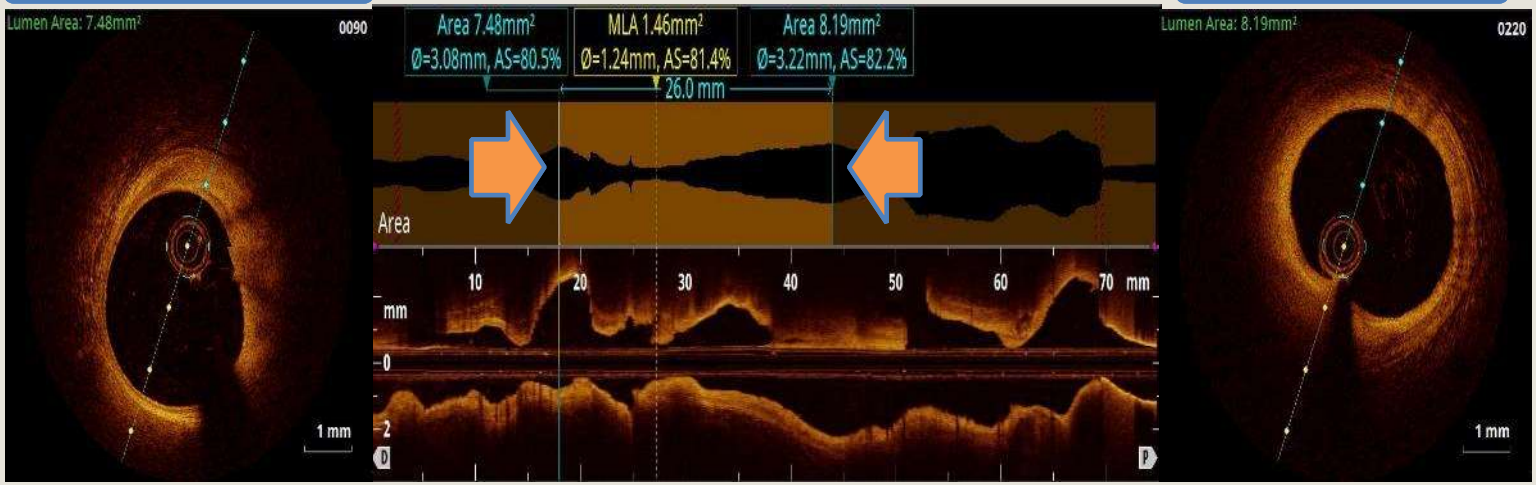
Identify Reference Segments (Prox & Dist)

Choose Stent Length

STRATEGIC TREATMENT ASSESSMENT
- **Vessel Size and Lesion Length Assessment**

DISTAL REFERENCE

PROXIMAL REFERENCE



AREA MEDIA 7.83 (PROX E DIST)

Identify Landing Zones

1) Scroll reference vessel markers to distal "normal" OCT lumenogram

2) Is this a safe place to land the distal stent edge?

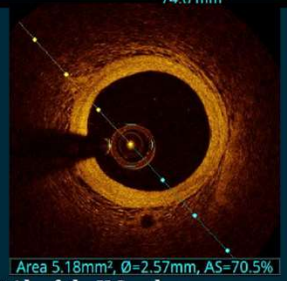
The more visible the EEL the safer your landing zone

3) Scroll reference vessel markers to proximal "normal" OCT lumenogram

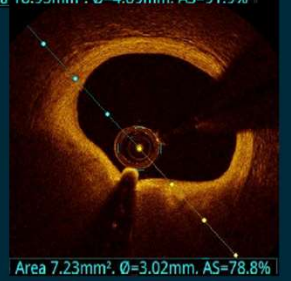
4) Is this a safe place to land the proximal stent edge?

The more visible the EEL the safer your landing zone

5) Adjust the length to an available DES size at the "more normal" reference



Lesion length 33 mm

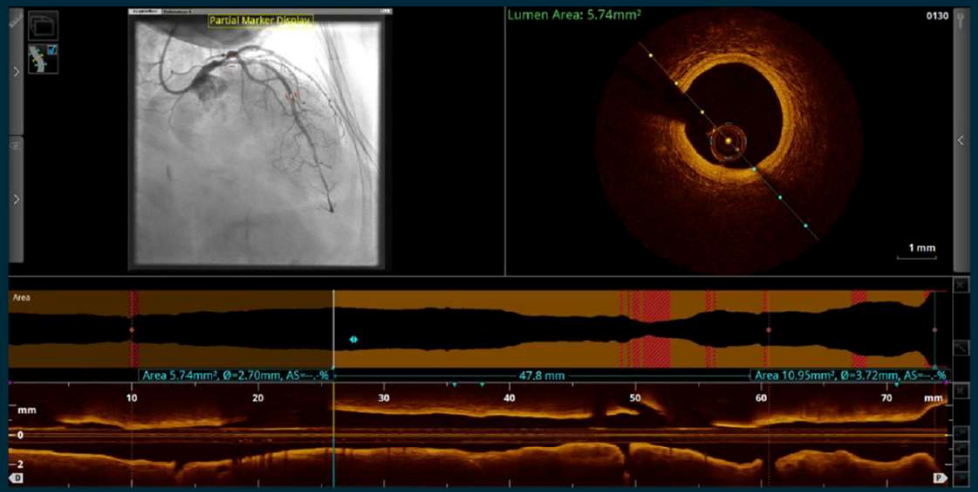


Courtesy of Dr. Ziad A. Ali

OCT-Guided Length

Identify:

- "Normal" reference segments
- Adjusted DES size

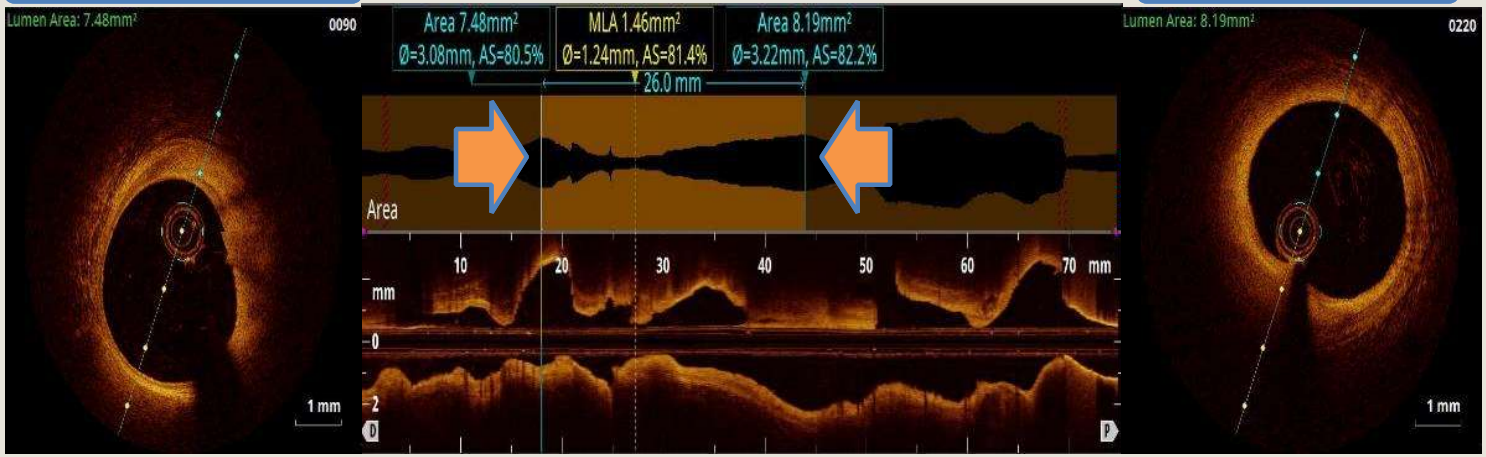


Case courtesy of Dr. Ziad A. Ali

LESION LENGTH ANALYSIS

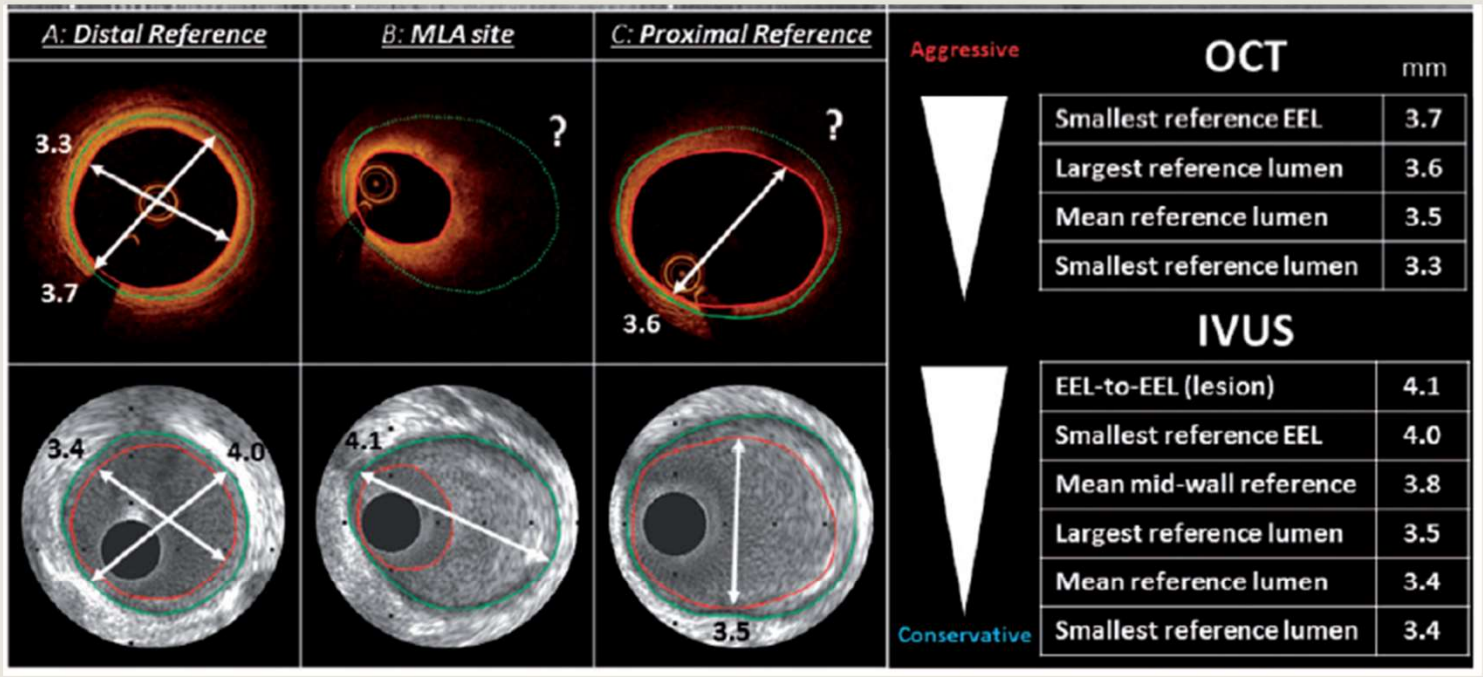
STRATEGIC TREATMENT ASSESSMENT
- Vessel Size and Lesion Length Assessment

DISTAL REFERENCE | **PROXIMAL REFERENCE**

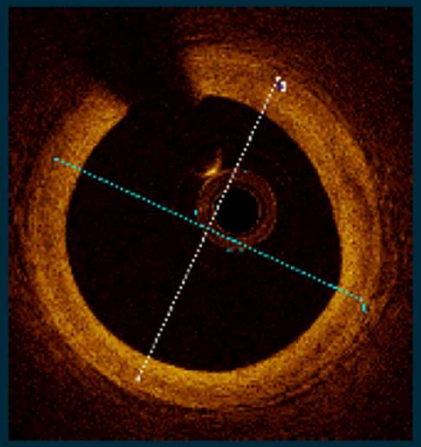


AREA MEDIA 7.83 (PROX E DIST)

3.Diameter
Choose Stent Size (vessel size assessment)

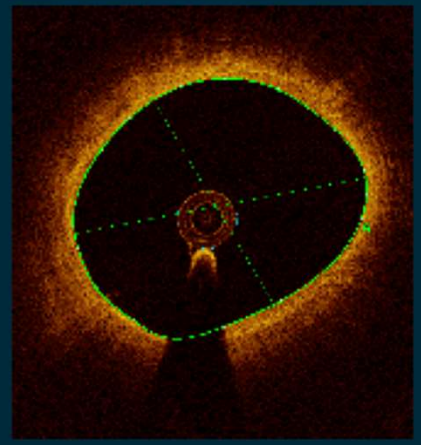


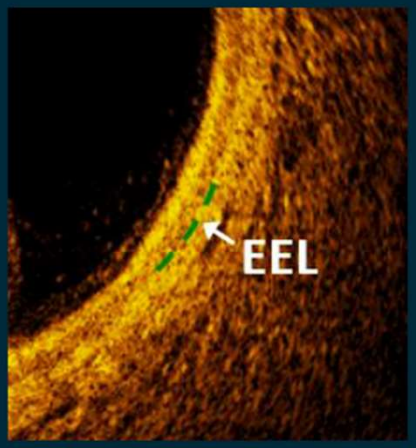
OCT Stent Sizing Algorithm



PRE-PCI OCT

Can the EEL be identified at the distal reference segment to allow vessel diameter measurement?



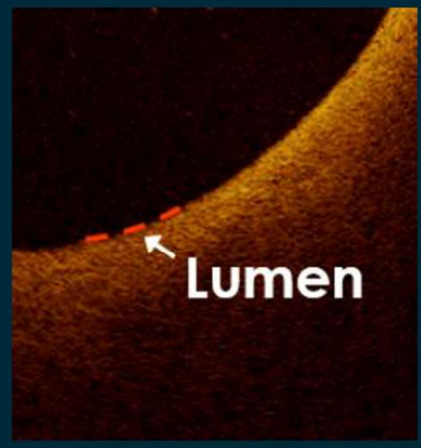


YES

Stent diameter decided by OCT measurement of mean EEL to EEL diameter rounded down to nearest stent size[1]

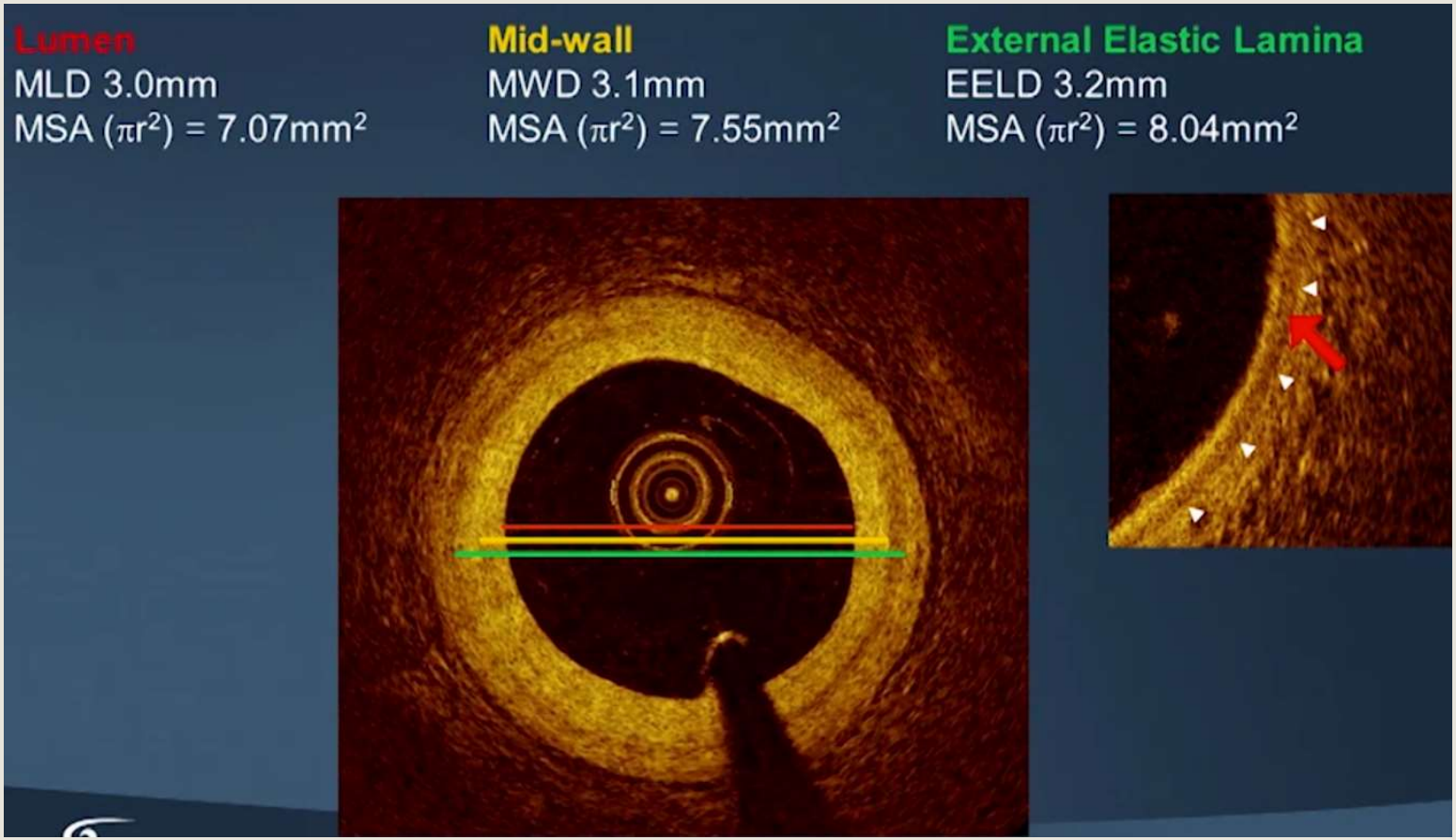
NO

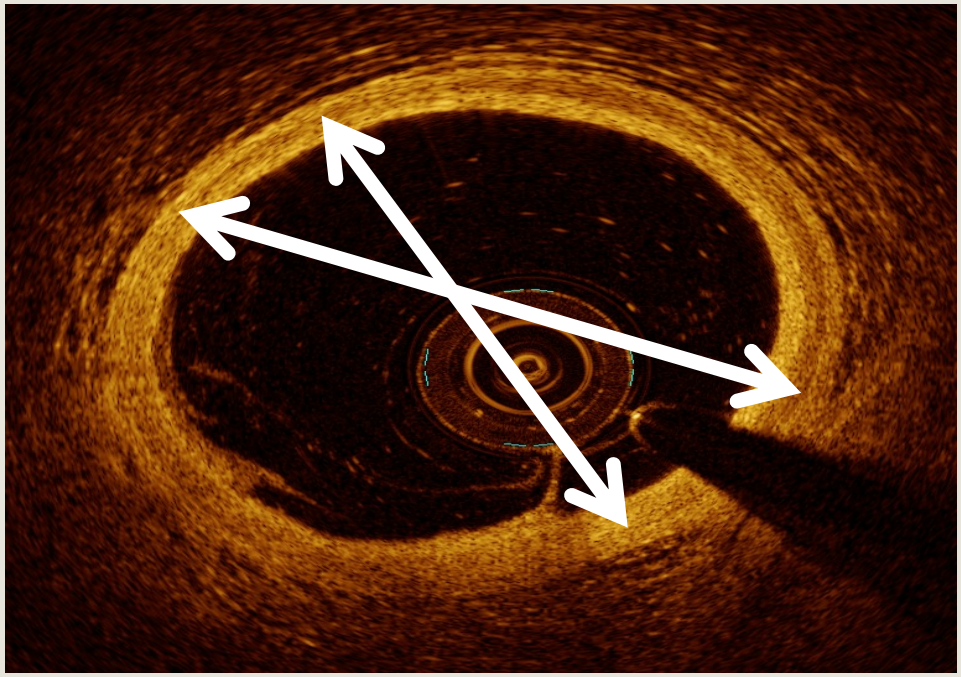
Stent diameter decided by OCT measurement of mean lumen diameter rounded up to nearest stent size[2]

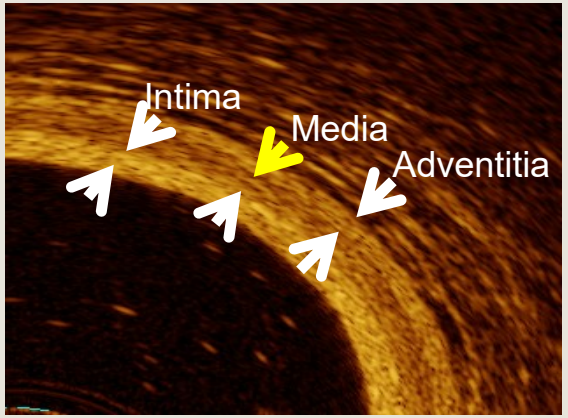


1. Ali, Z., et al., ILUMIEN III Study, Lancet Journal, 2016; 1-11. 2. Shlofmitz, E. et al. Algorithmic Approach for OCT Guided Stent Implantation During PCI. Intervent Cardiol Clin 7 (2018) 329-344.

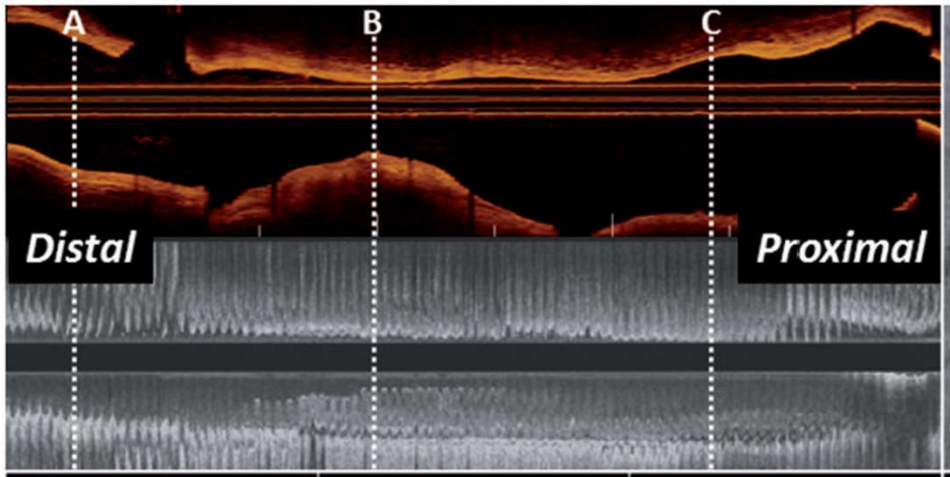
3.Choose Stent Size (vessel size assessment)

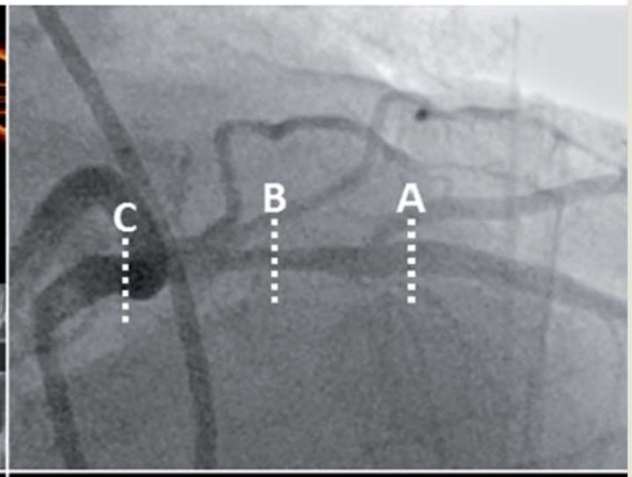


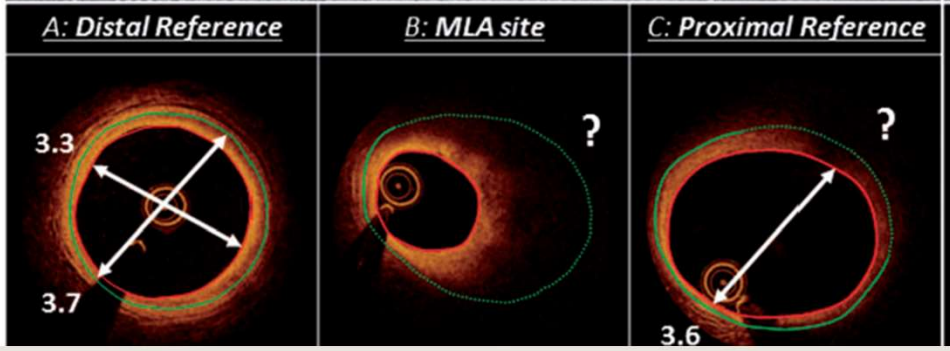




EEL identified by yellow arrow







Aggressive

OCT	mm
Smallest reference EEL	3.7
Largest reference lumen	3.6
Mean reference lumen	3.5
Smallest reference lumen	3.3

IVUS

- From a pratical standpoint a ***distal lumen reference (either EEM or lumen)*** based sizing may represent a safe straightforward approach with subsequent optimization of the mid and proximal stent segment.
-
- Specifically the ***mean distal Lumen diameter*** with up rounding stent 0,25 mm may be used or the ***mean EEM*** (2 orthogonal measurements) with down rounding to the nearest 0.25 mm stent sizing

17° Meeting
CardioLucca
Heart Brings Heart 2023

Lucca,
22-24 Giugno
2023
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Post-PCI OCT | Optimize

MEDIAL DISSECTION | **APPOSITION** | **EXPANSION**

17° Meeting
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Lucca,
22-24 Giugno
2023
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SECTION 4

Medial Dissection

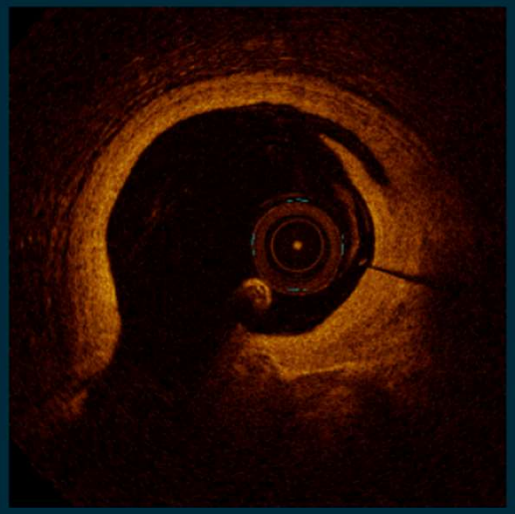
Dissections

Address Significant Dissection[1]

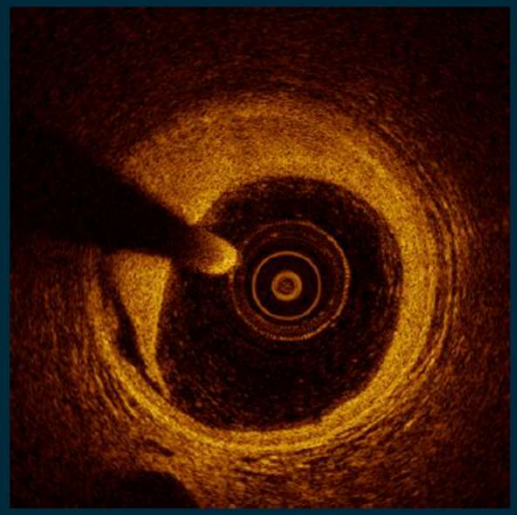
Dissection penetrates medial layer, and is greater than 1 quadrant arc

Common Practice[1,2]

Place additional stent (particularly for distal dissections)



Intimal



Medial

Intramural Hematoma

Edge Dissection: no major edge dissection in the proximal or distal reference segments defined as a location that is 5 mm from the edge of the stent,extends to the medial layer with potential to provide flow disturbance (defined as ≥60° of the circumference of the vessel at site of dissection and/or ≥ 3mm in lenght of the dissection flap

Tissue Protrusion/Prolapse

- Tissue Prolapse in the context of ACS is more likely to have consequences than in more stable clinical setting

Edge Dissection

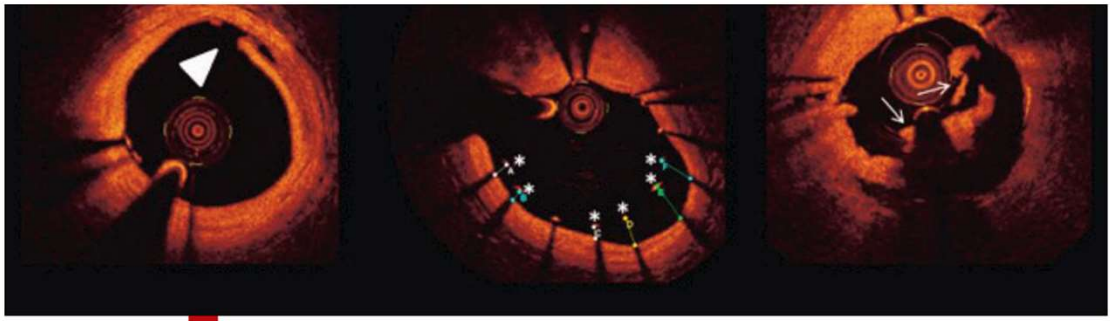
- Dissection > 200**µ** lenght at the distal stent edge is an indipendent predictor of MACE

Edge Dissection
Width >200um
Stent edge <5mm

Mal-apposition
Stent-lumen >200um

Thrombus
>200um

Luminal narrowing MLA<4mm^2



Additional Stent

Additional Post-dilatation

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22-24 Giugno
2023
Centro Congressi
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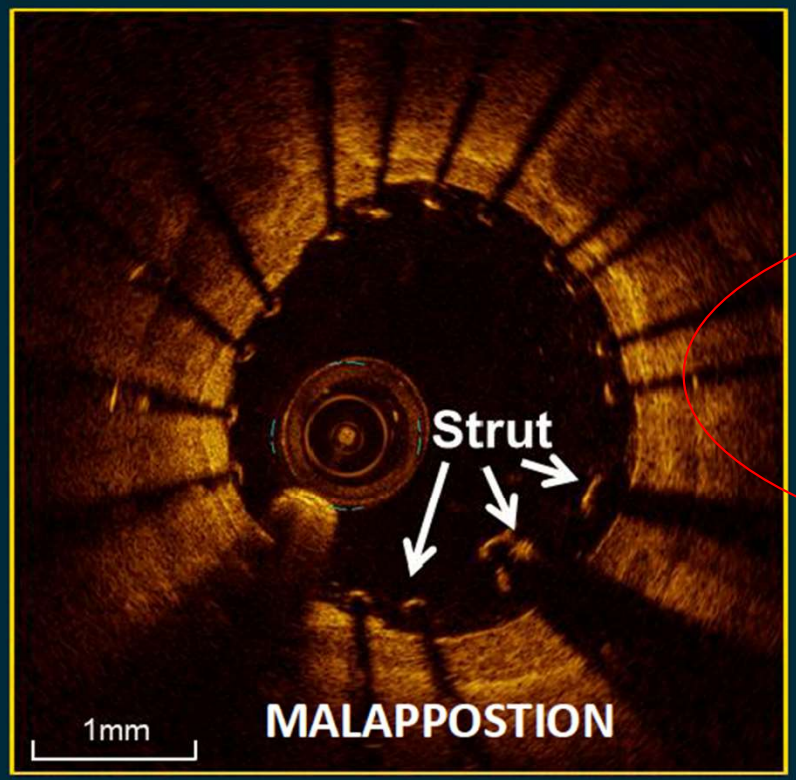
SECTION 5

Apposition

Apposition

If the stent struts are in contact with the artery wall, the stent is apposed



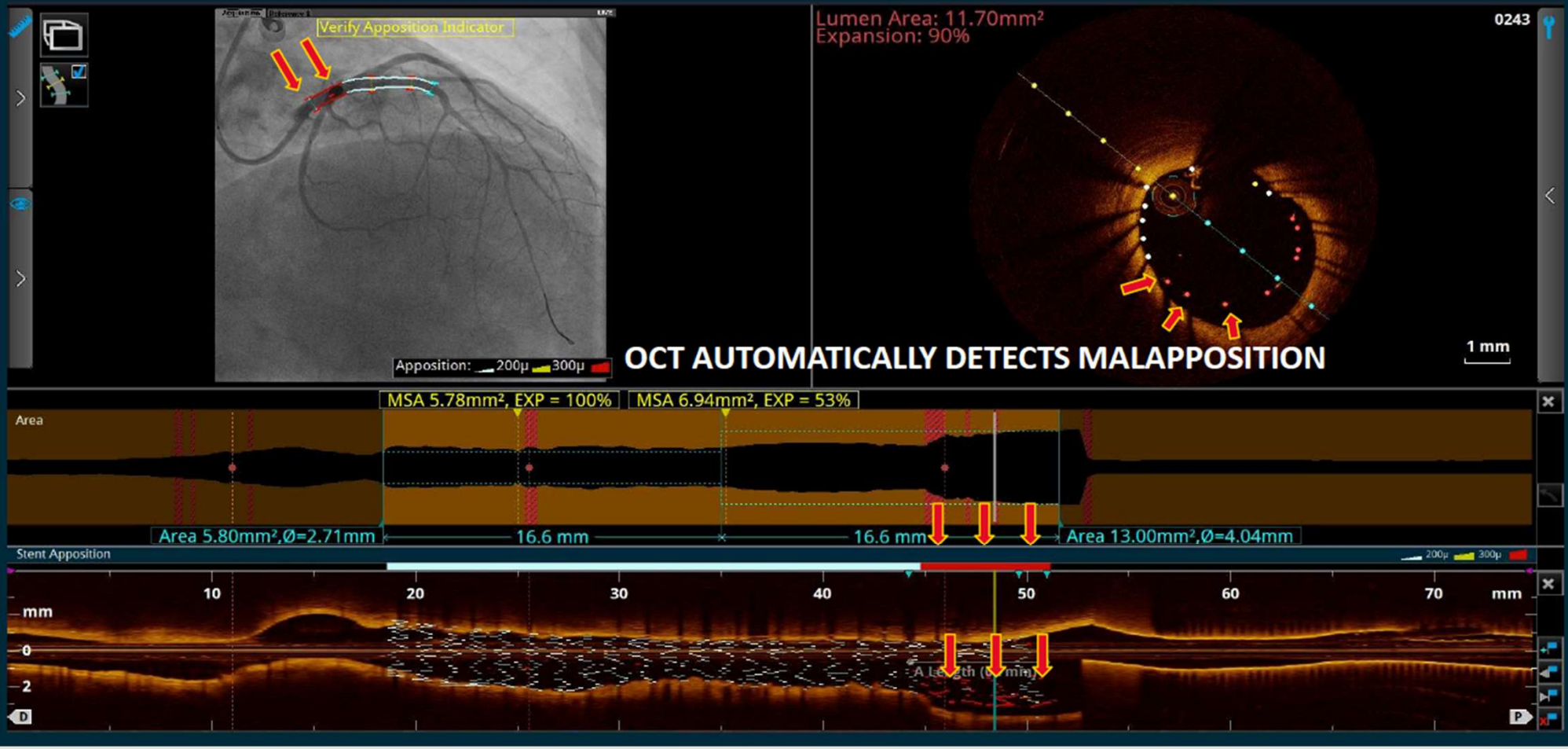
Address Gross Malapposition

- Longer than 3 mm,[1] and ≥0.3 mm from wall[2]

Common Practice[3]

- Dilate with semi-compliant balloon at low pressure

Apposition Indicator



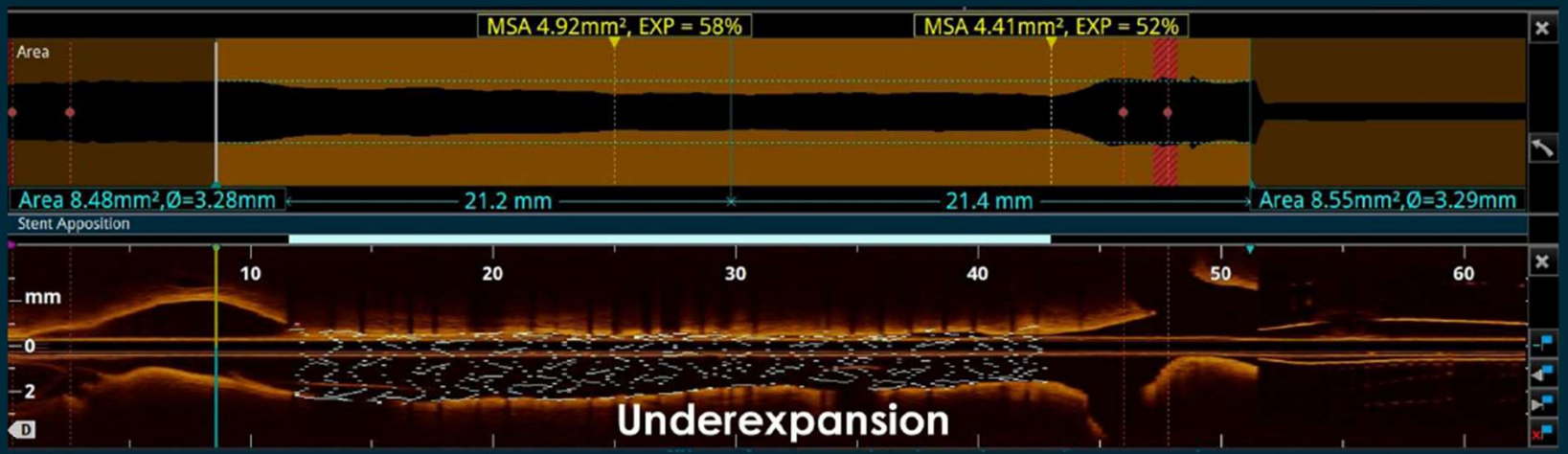
SECTION 6

eXpansion

Stent underexpansion is established as a major predictor of stent failure (restenosis/thrombosis)
Stent expansion describes the minimum stent CSA either as an absolute measure (absolute expansion) or compared with the predefinite reference area (relative expansion: prox-dist-average)

eXpansion

If the stent is expanding the lumen, holding the lesion close to, or greater than, the normal reference segment, the stent is expanded.



GOAL

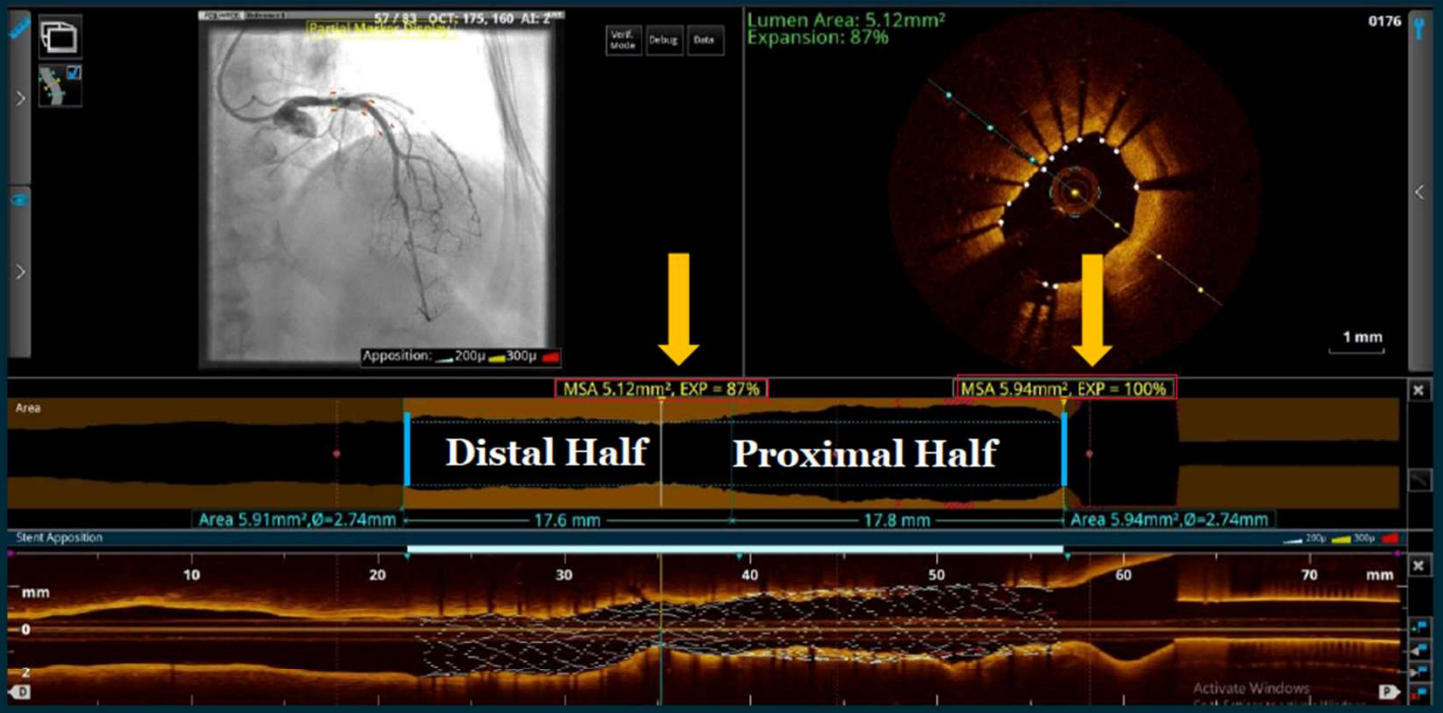
ACCEPTABLE = MSA ≥ 80% OF MEAN REFERENCE LUMEN AREA[1]

OPTIMAL = MSA ≥ 90% OF MEAN REFERENCE LUMEN AREA[1]

Determine Expansion / MSA - Dual

Fully automated expansion display

- ROI automatically detected
- Expansion automatically displayed

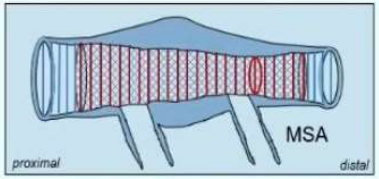


- **Determine your proximal half MSA compared to your proximal reference**
- **Determine your distal half MSA compared to your distal reference**

Definitions of 10 stent expansion indexes

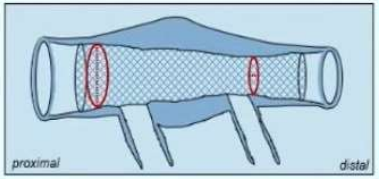
MSA

Minimum stent area in the entire stent



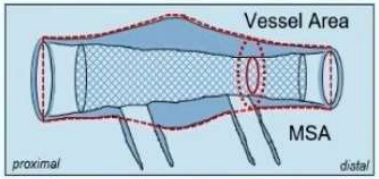
Stent Asymmetry

$$\frac{\text{Minimum Stent Diameter in the entire stent}}{\text{Maximum Stent Diameter in the entire stent}}$$



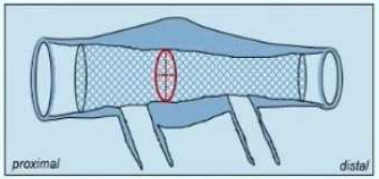
MSA/Vessel Area Stent Exp

$$\frac{\text{MSA}}{\text{Vessel Area at MSA}} \times 100$$



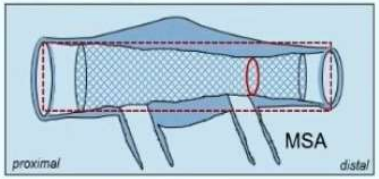
Stent Eccentricity

$$\text{Minimum of } \frac{\text{Minimum Stent Diameter}}{\text{Maximum Stent Diameter}}$$



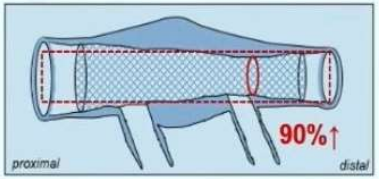
Conventional Stent Exp

$$\frac{\text{MSA}}{\text{Average of Proxi and Dist RLA}} \times 100$$



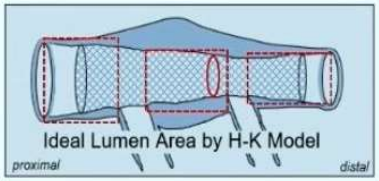
IVUS-XPL Criteria

Minimum Lumen Area
>90% of distal reference lumen area



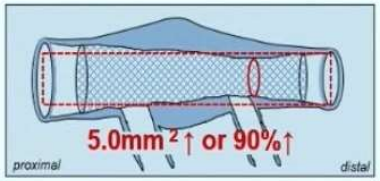
Minimum Stent Exp by H-K Model

$$\text{Minimum of } \frac{\text{Stent Area}}{\text{Ideal Lumen Area}} \times 100$$



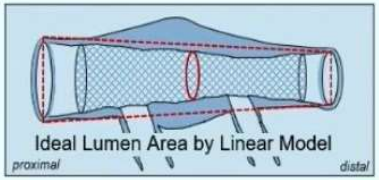
ULTIMATE Criteria

minimum lumen area
>5.0mm^2 or
>90% of distal reference lumen area



Minimum Stent Exp by Linear Model

$$\text{Minimum of } \frac{\text{Stent Area}}{\text{Ideal Lumen Area}} \times 100$$

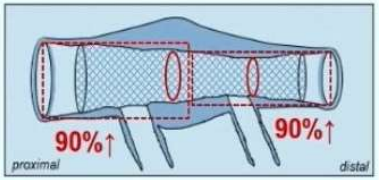


ILUMIEN IV Criteria

$$\frac{\text{Proximal MSA}}{\text{Proximal Reference Lumen Area}} \times 100 \ (\geq 90\%)$$

And

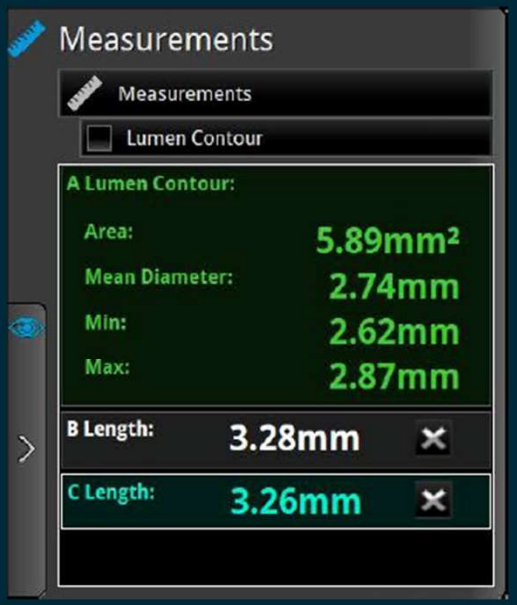
$$\frac{\text{Distal MSA}}{\text{Distal Reference Lumen Area}} \times 100 \ (\geq 90\%)$$

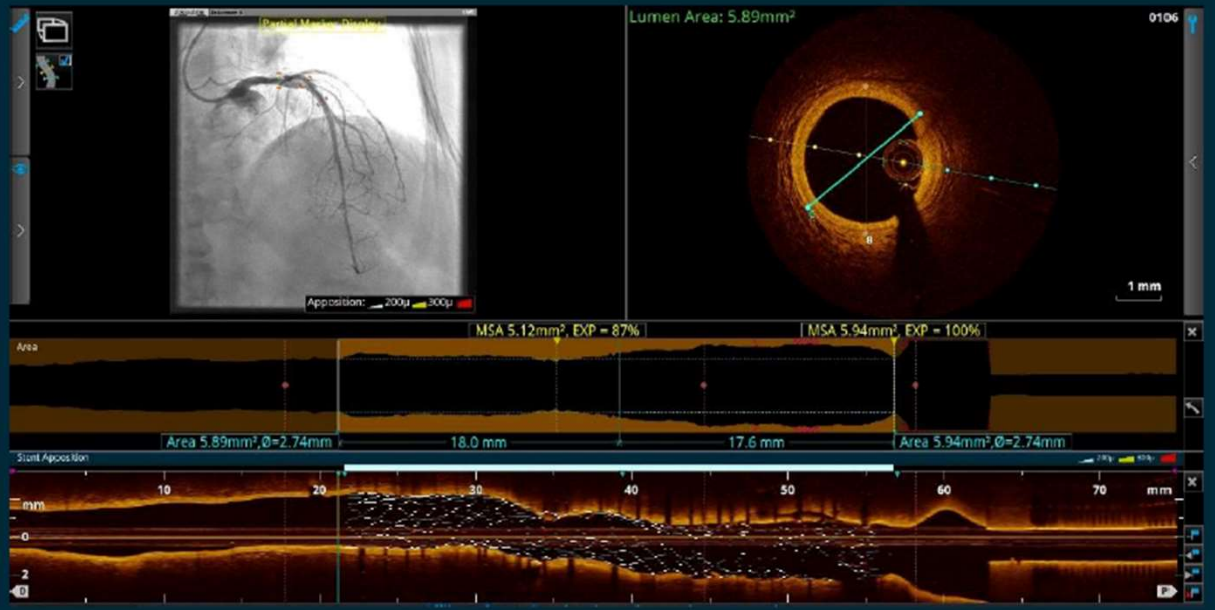


OCT Guided Optimization of Underexpansion

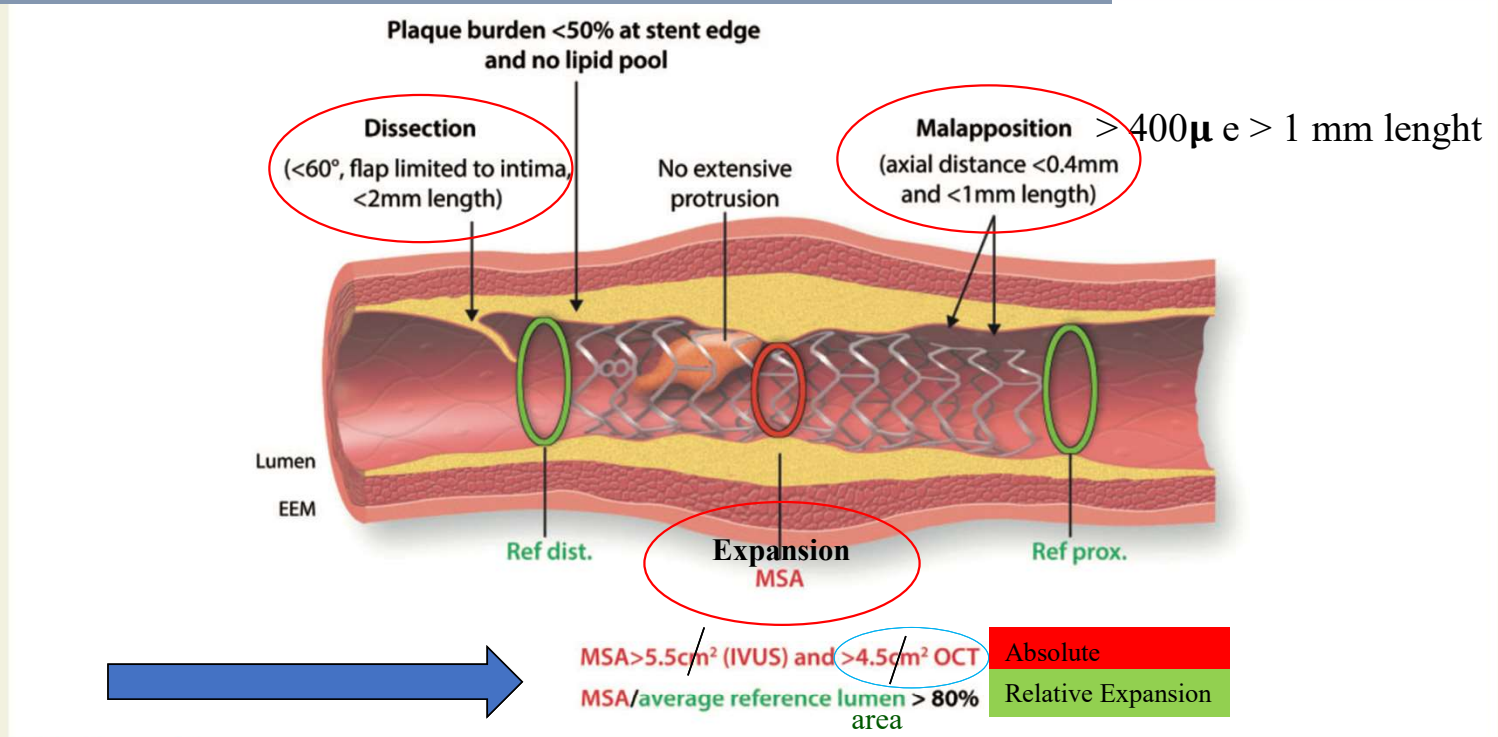
The post-PCI OCT is used to choose the balloon size for post-dilation in the segment of stent with underexpansion

Mean EEL = 3.27, therefore a 3.25 mm balloon should be used for post-dilation





Post-Procedural Assessment and Complication



Take home figure Summary of post-percutaneous coronary intervention optimization targets. The most relevant targets to be achieved following stent implantation in non-LM lesions are shown. These include optimal stent expansion (absolute as well as relative to reference lumen diameter); avoidance of landing zone in plaque burden >50% or lipid rich tissue; avoidance of large malapposition regions, irregular tissue protrusion, and dissections. Thresholds provided reflect the consensus of this group. Some are based on consistent and robust prospective data (e.g. stent expansion, landing zone) and others are less established (e.g. malapposition).

Conclusion

- The interventional community is moving towards comprehensive approaches in PCI, integrating anatomical information with imaging and function
- Integration of routine IVI for PCI has the potential to improve procedural safety and clinical outcomes.

No excuse for not using !